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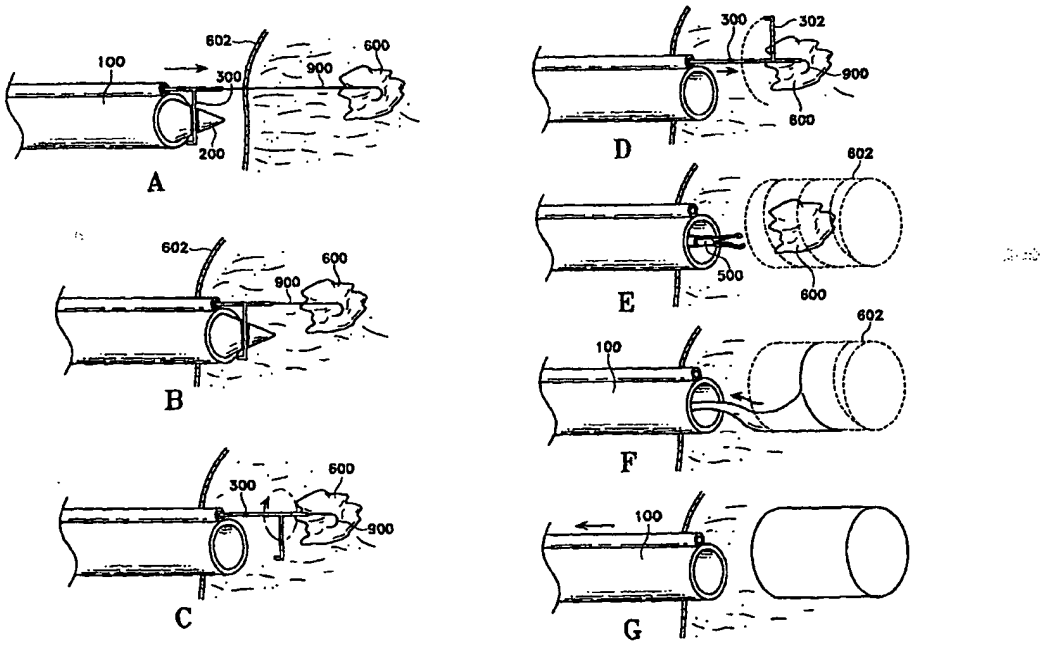

(57) Abstract

This is a device for percutaneous tissue sampling or excision. In particular, it uses a rotating cutter which produces a helically cut, discrete tissue mass that is removable through a comparatively much smaller access member. The tissue mass is easily reconstructed to its original form and orientation once taken from the body for further study.

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PERCUTANEOUS TISSUE REMOVAL DEVICE

RELATED APPLICATION

This is a continuation in part of U.S. Ser. No. 09/145,487, filed September 1, 1998, now pending, the entirety of which is incorporated by reference.

FIELD OF THE INVENTION

This invention relates to a device and to a related procedure for percutaneous tissue sampling or excision. In particular, it uses a rotating cutter which produces a helically cut, discrete tissue mass that is removable through a comparatively much smaller tissue access device. The tissue mass is easily reconstructed to its original form and orientation once taken from the body for further study.

BACKGROUND OF THE INVENTION

Despite the advances made in technologies such as medical imaging to assist the physician in early stage diagnosis and treatment of patients with possible atypical tissue such as cancer, it is still often necessary to sample difficult-to-reach organ or tissue lesions by biopsy to confirm the presence or absence of abnormalities or disease.

A disease for which biopsy is a critical tool is breast cancer. This affliction is responsible for 18% of all cancer deaths in women and is the leading cause of death among women aged 40 to 55. As with many diseases and other types of cancer, early detection and diagnosis of breast cancer is critical in providing the best chance of survival.

In the majority of cases, detection of the disease is first made when a patient discovers a palpable mass through self-examination and consults her physician. For breast lesions that are more difficult or impossible to detect through palpation, diagnostic techniques such as x-ray mammography and, more recently, digital mammography, and scintimammography are invaluable. Other techniques such as ultrasound, magnetic resonance, the Dilon gamma camera, position emission tomography, MIBI, computed topography, fluoroscopy, thermography, transillumination and diaphanography can also be used to help determine the presence and nature of suspect tissue.

Of these technologies, the primary clinical diagnostic tool for the detection of breast cancer is x-ray mammography. Over 15 million mammograms are performed each year in

the United States alone. Mammography uses x-rays to image breast tissue, identifying areas of high density as possible lesions.

Unfortunately, the limitations of technologies such as mammography in accurately detecting precancerous or cancerous lesions in the breast are significant. Among these limitations is the fact that only one out of every five lesions discovered through x-ray mammography proves to be cancerous. Roughly 25% of women have dense breast tissue, which is notoriously difficult to inspect via mammography. Also, mammography is generally less effective for women under 40 years of age. For younger women, therefore, self-examination for palpable lesions or ultrasound examination is important. However, neither of these techniques is able to detect microcalcifications, important possible precursors to cancer.

As long as there is a degree of uncertainty associated with these various diagnostic techniques, biopsies must be performed to sample the suspicious tissue to determine its exact nature and pathology.

In the detection and treatment of breast cancer, there are two general classes of biopsy: the minimally invasive percutaneous fine or core needle biopsy and the more invasive surgical or "open" biopsy.

Open biopsies, both incisional and excisional, are advisable when suspicious lumps should be removed in their entirety or when core needle biopsies don't give complete information about the nature of the lesion.

One such type of open biopsy is the wire localization biopsy. Such a procedure includes the following steps: first, a radiologist inserts a wire into the breast under x-ray guidance to mark the location of the suspect tissue. The tissue is then removed by a surgeon for examination by a pathologist. Although large tissue samples are removed by this technique, the risk of permanent disfigurement, the attendant morbidity and mortality risks associated with surgery, and long hospital recovery times are but three of the many disadvantages associated with open surgical biopsies.

Of the less invasive class of percutaneous biopsies, the least invasive is known as a fine needle aspiration biopsy (FNAB). For palpable lumps, a physician inserts a needle attached to a syringe directly into the lump to obtain a cell sample, which is then examined by a cytologist. For non-palpable lesions identified by x-ray mammography or other diagnostic tool, fine needle aspiration biopsies are often performed under stereotactic or

ultrasonic guidance. Under stereotactic guidance, multiple mammograms are taken of the breast under compression and the images are analyzed by a computer to determine the location of the suspect lesion in three dimensions. The physician then penetrates the breast with a needle, targeting the suspect region and removing a small number of cells. Alternatively, in the case of a nonpalpable mass, ultrasound may be used to guide the FNAB in real time in a noncompressed breast. There are two significant drawbacks to fine needle aspiration biopsy: first, several specimens must be taken to ensure the lesion is well-sampled. Secondly, the limited size of the specimens obtained under fine needle aspiration biopsy dictate that a skilled cytologist be involved to analyze the suspect cells out of context of the surrounding healthy tissue. Success varies widely. False negatives have been reported to vary from 1 to 31%, and false positives from 0 to 11%.

A second type of percutaneous needle biopsy used to obtain a larger specimen is known as a core needle biopsy. With this procedure, a larger needle, such as the Tru-Cut needle, is inserted into the breast via an incision in the skin with or without the aid of stereotactic or ultrasonic guidance. A coring needle, which may be spring-loaded, is then inserted into the breast to obtain a single core sample of tissue, preferably through the center of the lesion. The larger specimen obtained by this technique can be more accurately read by a pathologist, who can analyze the suspect cells in the context of the surrounding tissue. Examples of such devices are described in U.S. Patent No. Re. 34,056 and U.S. Patent Nos. 4,944,308 and 4,953,558.

Traditionally, as with fine needle aspiration biopsies, core biopsies require multiple core samples, typically four to twenty, to ensure an accurately representative sample of the suspect region is profiled. This means that as many as twenty separate needle insertions must be made into the breast through the skin.

More recently developed needle biopsy technologies are directed to solving this problem by allowing multiple samples to be obtained through a single incision, such as that described in U.S. Patent Nos. 5,709,697 and 5,782,775. One such technology, described in U.S. Patent Nos. 5,526,822, 5,769,086, and 5,775,333, utilizes a trocar-tipped probe, which is positioned in the breast under stereotactic or ultrasonic guidance to align the suspect lesion with an aperture that extends along a specified length of the probe. The tissue is then sucked into the aperture wherein a rotating cutter in the probe is advanced distally to cut and capture tissue specimen into the probe lumen. The cutter is then withdrawn,

transporting the specimen to a tissue collection chamber. Next, the probe, which is still in the breast, is radially rotated in position through a desired angle to align the aperture with another target tissue area. The steps of rotation, cutting, and collection, which can be automated and assisted by vacuum, are repeated until the desired number of samples is obtained.

Although this type of device requires only a small, single incision to obtain a number of core samples, each sample is still limited in size, requiring excision of multiple specimens for accurate pathologic diagnosis. As with other percutaneous excisional devices in which multiple specimens must be obtained, it is often difficult to reconstruct the spatial location and orientation of the suspect tissue as it resided in the breast prior to excision, resulting in a concomitantly difficult pathological analysis. In fact, because of the difficulty of reconstructing the biopsy samples, pathologists will assume that any cancer found in the tissue sample had a dirty margin.

Another type of percutaneous excisional breast biopsy device designed to obtain a single suspect tissue sample up to 20 mm in diameter is generally described in U.S. Patent Nos. 5,111,828, 5,197,484, and 5,353,804. This device, however, requires the use of a relatively large diameter cannula to obtain an adequate specimen size.

What is needed is a small-diameter percutaneous excisional biopsy device that allows a physician to obtain, in a minimally invasive manner, a relatively large tissue specimen through a small incision. Further, what is needed is a device that can obtain a specimen large enough for a complete, accurate and satisfactory pathologic determination, obviating the need for obtaining multiple core specimens and reconstructing them *ex vivo*.

SUMMARY OF THE INVENTION

This invention relates to devices and procedures for removing integral volumes of tissue via percutaneous access. The diameter of the volume removed using this invention is typically larger than the diameter of the access device. Depending upon the size of the device selected, the inventive device may be used for biopsy samples or for excision of larger amounts of tissue containing "suspicious areas" or tumorous masses. The tissue mass removed is typically continuous in form. Because of the method in which the device operates, the trauma caused by removal of the chosen volume is significantly lessened as compared to other available devices. The tissue mass removed is readily reassembled into

a discrete mass which has the same form and orientation as the mass had in the body.

The procedure involved the steps of selecting a target tissue mass. A trocar, tubular vessel removal member, and a cutting member are introduced percutaneously to the vicinity of the volume to be removed. The cutting member is positioned so that, as it is advanced and turned (after the trocar is removed), the cutting member produces a generally cylindrical mass of tissue having a circular cut at the front and back end of the cylinder and a spiral cut through the cylinder. The spiral-cut cylinder may be removed after the cutting is completed or during the step of producing that spiral cut. The spirally cut tissue is preferably then reformed into its initial cylindrical shape for further analysis or pathology. The step of cutting may be variously by the use of RF, ultrasound, or mechanical cutters, or by combinations of the three.

This procedure may be used in any internal, preferably soft, tissue, but is most useful in breast tissue, lung tissue, prostate tissue, lymph gland tissue, etc. Obviously, though, treatment and diagnosis of breast tissue problems forms the central theme of the invention.

The components typically used in the inventive procedure include a tissue removal member typically having two lumens. The larger lumen is for the removal of excised tissue from the targeted body site and the smaller lumen, which need not be continuous but may be simply a positioner loop or the like, is used for positioning of the cutting member. A trocar fits within the larger lumen in the tissue removal member and is used to penetrate the skin and tissue and thereby to position the distal end of the tubular tissue removal member in the vicinity of the tissue volume to be removed.

The cutting member has a long shaft that typically is placed within the smaller lumen of the tissue removal member. The cutting member is both advanced and rotated so that a generally cylindrical mass of tissue is produced at the chosen site. The lesion or tumor "suspicious mass" is to be situated within that chosen cylindrical region.

The tissue, while it is being cut from or after it has been cut loose from the body by the cutting member is then removed through the large lumen of the tissue removal member, perhaps using an auger-like device to carry the tissue sample to an external collector. Desirably, the removed tissue is placed in sample receptacle for later study.

Generally, the region to be excised is identified using stereotactic indexing apparatus as is well known in the art. It is typical that the rotation and advancement of the

cutting member is controlled using an automated controller box.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows an assemblage of the components, as in a kit, which make up the inventive tissue removal device.

Figures 2A to 2G show variations of the tissue removal member and their relation to the rotatable cutting member.

Figure 3 shows another variation of the tissue removal member, its associated tissue cutting member, and a desirable manner for transporting the accumulated tissue for later analysis.

Figures 4A and 4B show, respectively, a partial cutaway side view and an end view of a variation of tissue removal member and in particular, show an augering device to assure orderly removal of the excised tissue from the target area.

Figure 5 shows another variation of the tissue auger in partial cutaway side view within the tissue removal member.

Figure 6A shows a top view and Figure 6B shows a side view of a trocar which fits within the tissue removal member and supports the tissue cutting member as it is introduced into the target tissue region.

Figures 7A to 7D show variations of the shape of tissue cutter.

Figures 8A to 11B show, variously, front quarter views and top views of configurations of the cutting members shown in Figures 7A to 7D.

Figures 12A to 12B show a two-part expandable diameter cutting member and depict the steps of the cutting surface expansion.

Figure 13A shows a front quarter view, Figure 13B shows an end view, Figure 13C shows a side view, and Figure 13D shows a top view of an extendible mechanical cutting member.

Figure 14A shows a front quarter view, Figure 14B shows an end view, and Figure 14C shows a side view of mechanical cutting member.

Figure 15A shows a front quarter view, Figure 15B shows an end view, and Figure 15C shows a side view of a cutting member having a two-part cutting surface which is extendable from the shaft of the cutting member. Figure 15D shows a typical cross-

section of the two part cutting surface.

Figure 16 shows a variation of the cutting member in which a mechanical cut is made using rotating, generally circular, blades.

Figure 17A is a front quarter view of a cutting member having a single leading cutting surface. Figure 17B is a cross-sectional view of the radial blade of the cutting member shown in Figure 17A showing the cutting angle.

Figure 18A is a front quarter view of a multiple blade, rotatable cutting member and Figure 18B is a partial cross-sectional view of the cutting surfaces for that cutting member.

Figure 19A is a side view of a typical endoscopic snare suitable for use in grasping the removed tissue in accordance with this invention. Figure 19B shows a harpoon spear which is also suitable for accessing and grabbing tissue for use in removing selected tissue when using this device. Figure 19C is an expandable braid and optional allied hook also suitable for retrieving tissue using this invention.

Figures 20A through 20G show a typical procedure sequence using the invention described herein and, in particular, the kit selection found in Figure 1.

Figures 21A through 21H show a variation of a typical procedure sequence using the invention described.

DESCRIPTION OF THE INVENTION

As noted above, this invention relates to devices and procedures for removing integral volumes of tissue, typically breast tissue, via percutaneous access. The diameter of the tissue volume removed using this invention is larger than the diameter of the access device. Depending upon the size of the device selected, the inventive device may be used for biopsy samples or for excision of larger amounts of tissue containing "suspicious areas" or tumorous masses. Because of the method in which the device operates, the trauma caused by removal of the chosen volume is significantly lessened as compared to other available devices. In addition, the tissue mass removed can be readily assembled, after exit from the body, into a discrete mass that has the same form and orientation as the mass had in the body.

In general, the procedure involved is this: first, a target tissue mass is selected. A trocar, tubular vessel removal member, and a cutting member are assembled and introduced percutaneously to the vicinity of the volume to be removed. The cutting member is

positioned so that, as it is advanced and turned (after the trocar is removed), the cutting member produces a generally cylindrical mass of tissue having a circular cut at the front and back end of the cylinder and a spiral cut through the cylinder. The spiral cut cylinder may be removed as a continuous strip after the cutting is completed or during the step of producing that spiral cut. Alternatively, to prepare for pathology an essentially cylindrical biopsy sample that was obtained by a conventional coring method, a cutting member may be simultaneously rotated and translated with respect to the biopsy sample to helically cut the biopsy sample; this may be accomplished in several ways, such as by rotating and translating the biopsy sample, or by rotating and translating the cutting member, or by rotating one and translating the other, or by rotating the cutting member clockwise and the biopsy sample counterclockwise while translating one with respect to the other. The spirally cut tissue is preferably then reformed into its initial cylindrical shape for further analysis or pathology. The step of cutting may be variously by the use of RF, ultrasound, or by the use of mechanical cutters.

Figure 1 shows, in generic fashion, the components typically used in the inventive procedure. Tissue removal member (100) is shown in Figure 1 as typically having two lumens. The larger lumen is for the removal of excised tissue from the targeted body site and the smaller lumen is used for positioning of the cutting member (300), as will be discussed below. The trocar (200), which fits within the larger lumen in tissue removal member (100), is also shown. Trocar (200) is used to penetrate the skin and tissue and thereby to position the distal end of the tubular tissue removal member (100) in the region of the tissue volume to be removed.

Figure 1 shows a typical cutting member (300). Cutting member (300) has a long shaft that typically is placed within the smaller lumen of tissue removal member (100). The shaft is preferably hollow so as to allow it to follow a localization wire (900) that has been used to mark the tissue to be removed. When the cutting member (100) shaft is situated in the smaller lumen of tissue removal member (300), it is both advanced over the localization wire (900) and rotated about it so that a cylindrical mass of tissue is produced at the chosen site. The lesion or tumor is to be situated within that chosen cylindrical region.

The tissue, while or after it has been cut loose from the body by cutting member (300), is then removed, e.g., by a removal member (500) such as that shown in Figure 1.

Desirably, the removed tissue is placed in sample receptacle (700) for later study.

Generally, the region to be excised is identified using stereotactic indexing apparatus as is well known in the art. It is typical that the rotation and advancement of the cutting member (300) is controlled using a controller box (800) such as that depicted in Figure 1.

TISSUE REMOVAL MEMBER

Figure 2A shows a typical variation of the inventive tissue removal member (102). This variation includes a larger lumen member (104) and a smaller lumen member (106) that is exterior to the lumen (103) of large lumen member (104). For purposes of illustration only, a cutting member (108) is shown in the lumen (105) of small lumen member (106). Central to this invention is the concept that as the cutting member (108) is rotated by the physician user, it cuts a disc (or spiral as it is advanced) which is significantly larger in diameter than is the lumen (103) of large lumen member (104) of the tissue removal member (102).

In the inventive tissue removal members shown in Figure 2A and subsequent figures, the smaller lumen member carrying the cutting member may be fixed with respect to the larger lumen member. Alternatively, the smaller lumen member may translate with respect to the larger lumen member; the advantages of this will be seen with respect to Figure 2G and Figures 21A-G. Furthermore, the distal end of the smaller lumen member may be somewhat tapered or conical to aid in penetrating tissue.

Typically, large lumen member (104) is constructed from any of a large number of polymers typically used in this service, e.g., Nylons, reinforced Nylons, polyethylene, polypropylene, polyethylene terephthalate (PET), fluorocarbon plastics (e.g., Teflon), etc. The polymers may be reinforced by fibers or filled. As will also be discussed below, the tissue removal member may be reinforced or made radially expandable using coils or braids of metals, alloys, or polymers (natural or synthetic) included in the walls of the member. The walls may be made at least partially radio-opaque by introduction of, e.g., powdered tantalum, powdered tungsten, bismuth carbonate, and other known particulate and fibrous radio-opacifiers.

Figure 2B shows a similar tissue removal member (110). In this variation, the small

lumen tubular portion (112) is not exterior to the lumen (113) of large lumen member (114) but is instead within the large lumen member (114). Again, the rotating end rotatable cutting member (108) is shown positioned in the lumen (111) of small lumen tubular member (112). This variation has the obvious benefit of being somewhat smaller in overall diameter than is the variation shown in Figure 2A. However, the size of the cylinder that can be produced by the properly sized cutting member (108) is also somewhat smaller. This variation might, for instance, be better suited for gathering a biopsy sample than for performing a lumpectomy.

Figure 2C shows another variation in which the small lumen portion (116) of the tissue removal member (118) is spaced away from the interior wall of the large lumen (115). This variation is especially suitable for use with the helical tissue removal auger, which is discussed in significantly more detail below. It is also especially suitable for use with cutting members that expand or extend outwardly from that small lumen (116).

Figure 2D shows another variation of the tissue removal member (120). In this variation, the tubular portion of the outer member is elastically expandable. This is depicted by the expanded portion (122) shown in Figure 2D. An expandable outer tubular section is suitable with any of the variations described above. This variation, however, is expandable due to the use of a woven braid (124) and an elastomeric polymer forming the outer layer (126) of the device. An optional inner layer (128) is also depicted in Figure 2D but such an inner layer (128) is not, obviously, absolutely necessary. It is convenient and desirable, however. Figure 2D is a partial cutaway.

The expandable tissue removal member shown in Figure 2D is especially suitable for use with a cutting member (and its allied secondary or smaller tubular section (130)) that is significantly larger than the diameter of the outer tubing member. The whole cutting member and inner tubing may be urged through this expandable outer section for use at the chosen site.

Figures 2E-2G show variations of the inventive tissue removal member that include a cooling system for cooling or freezing tissue such as breast tissue or fat tissue. Cooling or freezing helps to physically stabilize the tissue during cutting to ease the cutting process and render a cleaner cut with less trauma to the surrounding tissue. It also helps to solidify the fat during cutting, whether using RF, ultrasound, a mechanical blade, or other cutting means. Cooling or freezing also helps to keep coagulum from forming on an RF or other

heat-producing cutting tool.

Figure 2E shows an inventive tissue removal member (180) having a closed system for cooling or freezing tissue. The large lumen member (181) has a U-shaped pipe (186) within the large lumen (181). Coolant flows through one leg of the pipe and returns through the other. The arrows show the direction of coolant flow. Large lumen member (181) provides thermal insulation. The coolant-carrying pipe (186) is exposed to the tissue at the open distal end of large lumen member (181), allowing heat to be transferred from the tissue to the cooling pipe (186). The coolant-carrying pipe (186) can be removed following cutting so that excised tissue may be removed through the large lumen (181).

Figure 2F shows a variation of the inventive tubular tissue removal member (188) having an open system for cooling tissue. The large lumen member (190) has one or more small lumens (191) through its wall, through which a biocompatible coolant such as cold saline can be pushed into the tissue. The coolant and any melted fat or blood may be aspirated through the large lumen (189). This system may be used in procedures in which the tissue removal occurs after all cutting is completed as well as in procedures in which the tissue is pulled into the tissue removal member (180) simultaneous with the cutting. The arrows show the preferred direction of coolant flow.

Figure 2G shows another variation of the inventive tubular tissue removal member (192) having an open system for cooling tissue. Small lumen member (196) translates with respect to large lumen member (194) so that its distal end is always close to the cutting end of the cutting member (300). The small lumen (195) is sized to accommodate cutting member (300) with enough clearance to deliver biocompatible coolant through it to the tissue in the vicinity of the tissue being cut. The coolant and any melted fat or blood may be aspirated through the large lumen (193) of the large lumen member (194). The arrows show the direction of coolant flow. It should be noted that suction may be applied as in either Figure 2F or 2G to remove melted fat, blood or other tissue or debris during the procedure, with or without cooling.

Figure 3 shows another variation of the inventive tubular tissue removal member (142), in this instance, having a center small tubing member (144). Of particular instance in this variation is the presence of a receiver (146) situated at the proximal end of the tubular tissue removal member assembly (140).

Of special interest is the specimen collector (148), which may be fitted within

receiver (146). It is within the scope of this invention to index the position of the tissue cutting member (150), here depicted as a simple "squared-J" shape, with the position of the tissue collector (148) so that as the tissue is removed through the tubular tissue removal member (142), it ultimately resides in the tissue collector (148) in the very position as found in the chosen collection site within the body. A cap (152) for the tissue collector (148) is also shown.

Figure 4A shows a variation of the tubular tissue removal member (160) having an outer tubular member (162), an integral receiver (164), and a tissue displacement auger (166).

In this variation of the inventive device, the cutter member (168) rotates in one direction, e.g., clockwise, and the auger (166) rotates in the other direction, counter-clockwise. In this way, the excised tissue leaves the cutting surface as it is separated from the remaining tissue and is newly-deposited in the form as found in the body, in the receiver (164).

In general, the auger (166) maintains the integrity and continuity of the removed tissue by maintaining the separation of the turns of the tissue as it passes from the distal end of the tubular tissue removal member (160) to the proximal end. The auger (166) may be stationary as the cutter advances in the tissue member (168) if the tissue is pulled from the proximal end.

It may be apparent that the tissue removal member (160) may be advanced (or stationary) as the cutting member (168) progresses spirally through the tissue to be excised. In many instances, movement is not necessary, however.

Figure 4B shows an end view of the device found in Figure 4A. In it may be seen the cutting member (168); which cutting member has a significantly larger diameter as it rotates than does the inner diameter of tubing member (162). The leading edge of auger (166) may also be seen in Figure 4B.

The diameter of auger (166) in this instance is fairly close in size to the inner diameter of outer tubing member (162). This tight clearance is not, however, necessary. For instance, Figure 5 shows a tubular tissue removal member having an auger (168) with vanes (170) having a significantly smaller diameter. Auger (168) provides a significant clearance between the tip of the vanes (170) and the interior lumen of outer tubular member (172). In some instances, it may be desirable to use a smaller diameter auger so to allow

for, for instance, a grasping device to slide between the auger and the interior of the wall, to grasp the tissue as it comes off the cutter, and to urge the excised tissue towards the proximal end of the tubular tissue removal member.

TROCAR

The trocar used in this assemblage is preferably one that fits within the inner lumen of the tubular tissue removal member. This permits the trocar to carry that member as it penetrates the outer skin and the tissue on the pathway to the selected site. The trocar used in this invention may simply be one having a sharp mechanical cutting surface or may be connected to one of any of known RF sources which generates energy for cutting tissue and, perhaps, cauterizing it as the initial incision is made.

Figures 6A-6B show a typical, but highly desirable, variation of a trocar (200) that is especially suitable for use in this assembly. Specifically, trocar (200) has a sharp leading pointed end (202), a sharp cutting edge (204) and, desirably, a transverse slot (206) for carrying the cutting member to the selected tissue site.

CUTTING MEMBER

The cutting members discussed herein are all similar in that each has a cutting surface, i.e., the portion of the device that meets the tissue and cuts a path whether that path is made by a mechanical cutter as with a knife blade or by an RF or ultrasound energy source. The cutting member may be attached to an RF or ultrasound source or may be made up of mechanical cutters or may be combinations of them. Often, the members are mechanically vibrated to produce a cutting motion. It is within the scope of this invention that the tissue itself be vibrated to produce a differential motion between the tissue and the cutting surface to create a mechanical cutting motion.

The cutting member preferably includes a hollow shaft that allows it to follow a localization wire used for marking the tissue to be removed. This hollow shaft is preferably electrically and thermally insulated from the localization wire, especially when an RF, ultrasound, or other similar cutter is used. The insulation may take the form of an insulated coating on the inside of the hollow cutter shaft or on the outside of the localization wire. Alternatively or additionally, the entire cutter shaft or localization wire may consist essentially of an electrically and/or thermally insulating material.

Figures 7A, 7B, and 7C schematically depict three shapes especially suitable for use as RF cutters. The tissue cutting member shape (300) shown in Figure 7A is generally referred to as the "L" shape. The cutting member has a shaft (302) and a radial member (304) and a very short axial cutting length (306). This shape is especially suitable when the pitch of the desired helix made in the chosen tissue, is quite small. The pitch of the cut helix should be no smaller than the length of axial cutting section (306).

Figure 7B shows a similar cutting member (310) also having a radial cutting surface (312) and an axial cutting surface (314). This shape is known as a "squared-J."

Figure 7C shows a "rounded-J" shaped cutting member (316). It also has an axial cutting surface (318). The radial cutting surface (320) is rounded.

Especially suitable for this service is the squared-J shaped cutting member (322) with a distal extension (324) as shown in Figure 7D. We have found that occasionally when approaching the boundary of lesions within, e.g., breast tissue, the cutting member variations shown in Figures 7A, 7B, and 7C may stray from the directed path. Distal extension (324) serves as an axial leader or guide and prevents any tendency of the cutter to wander or, indeed, to stop the tissue from being pushed away from the cutter. To further stabilize the movement of the cutter, it is sometimes desirable to insulate distal extension (324) with insulation (326) proximal of the tip (328) so to prevent enlargement by heating of the track that has been produced by the distal extension. In a cutting member having a distal extension (324), a localization wire may be used to further stabilize and guide the cutting member to the lesion. In the case where the cutting member follows the wire, the lumen of the hollow shaft may extend through the distal extension (324), with the distal tip (328) being open to the shaft lumen.

Figures 8A through 11B show shapes that are appropriate for tissue cutting members used in accordance with this invention when RF is applied to the cutter as the cutting energy.

Figures 8A and Figure 8B show a simple round wire for the cutting member. Figure 9A and 9B show a cutting member having a rectangular cross-section (332). Figures 10A and 10B show cross-section (334) having a knife edge (336). A sharpened knife edge such as (336) will focus the RF energy towards the leading edge of the cutting surface and facilitate movement of the device through the tissue. Again, it is within the scope of this invention that this variation of the invention be used as a combination

mechanical and RF cutter. Similarly, Figures 11A and 11B show a cross-section (338) that also has a serrated knife edge (340). The further limitation of surface area on the leading edge of the cutting member enhances the use of RF in the cutting member of the invented device.

The material making up the cutting members shown in Figures 7A through 11B is not central to this invention. The materials may be any of a variety of stainless steels, cobalt alloys, and other alloys typically used in this service.

Nonetheless, we have found that certain titanium-nickel alloys are particularly suitable for use with this device, particularly when the blades are used either as simple knife-edge cutters or as a combination of RF/mechanical cutters. This material is typically a 50/50 molar ratio alloy of titanium and nickel. Closely related alloys are the shape memory alloys that exhibit superelastic/pseudoelastic shape recovery characteristics. These alloys are well-known and are commonly referred to as "nitinol." See, for instance, U.S. Patent Nos. 3,174,851; 3,351,463; as well as 3,753,700. These alloys are characterized by their ability to be transformed from an austenitic crystal structure to a stress-induced martensitic (SIM) structure at certain temperatures, and return elastically to the austenitic shape when the stress is removed. These alternating crystalline properties provide the alloy with its superelastic properties. The nitinol forms of these alloys are readily commercially available and typically will undergo the austenite-SIM-austenite transformation at a variety of temperature ranges between -20 C and 30 C.

Figures 12A through 12D show a cutting member that is extendable from a delivery shape (as shown in Figure 12A) to a fully extended and deployed shape (as shown in Figure 12D). The cutting surface of this particular variation is desirably a superelastic alloy because of difficulty of unfolding the device without inducing strain upon the cutting member material.

Figure 12A shows device as delivered through the small lumen tubular member discussed above. The cutting member assemblage (350) has an outer tubing member (352) and a window (354) for exiting of cutting surface member (356). Cutting member (356) is slidably extendable through the lumen of cutting tubular member (352).

Figure 12B shows cutting member (356) emerging from window (354).

Figure 12C shows the further emergence of cutting member (356) and Figure 12D shows cutting member (356) fully emerged from cutting member shaft (352).

This variation of the invention allows the use of a fairly large diameter cutting member, e.g., one having a cutting radius (358) which is more than the overall outside diameter of the tubular tissue removal member for which it is deployed.

Figure 13A shows a tissue cutting member (360) that is used primarily for mechanical cutting although it obviously may be used as a combination of RF and mechanical cutter as well. We have observed that in the tissue found in the breast, cutting is facilitated by using a cutting surface at a nonperpendicular angle to the path of the cutter. When cutting a circle in tissue by rotating cutting member (360), cutting surface (362), which lies on a radius of the circle to be cut, is less effective than cutting surface (364), which does not lie on a radius. Cutting surface (364) provides an angular surface to the direction of cutting; that is, cutting surface (364) is not parallel to the shaft of cutting member (360), but is skew to it. As noted above, this device may be vibrated or the tissue to be removed may be vibrated to provide additional cutting action. A cutting surface that is pointed or serrated is also desirable.

Figure 13B shows an end view of the cutting member and the end cutting surface (362). Figure 13C shows a side view of the cutting member (360), while Figure 13D shows a top view of the same.

Figure 14A shows another variation of the mechanical cutting member (370). Each of the radially extending blades (372) and axially extending blades (374) has a triangular shape with a leading edge (376) which is positioned so to present an angular cutting surface to the tissue to be excised. As may be seen in Figures 14B and 14C, the triangular cutting blades have points (378) and (380), which serve to enhance the cutting capabilities of the depicted cutting member (370).

Figures 15A through 15D show an extendable cutting member (390). The cutting member (390) is made up of three members: a housing member (392), a guide track (394), and a cutting member (396). Guide member (394) and cutting member (396) are shown extended from the housing (392) in each of Figures 15A, 15B, and 15C. However, as is noted by the arrow in Figure 15A, the guide member (394) and cutting member (396) are extended from the housing. Such extensions are done upon arrival of the device at the selected excision area. Desirably, the blade or cutting member (396) is made of a sharpened superelastic alloy of the type discussed above. Similarly, a guide member (394) is also so constructed. This allows the blade and guide to be extended from the housing

(392) and retain a desired shape upon that extension. The blade member (396) is desirably oscillated in a saw-like fashion as depicted in Figure 15A as shown by the arrows in Figure 15A.

Figure 15B shows an end view of the cutting member. Figure 15C shows a side view of the tissue cutting member (390). It may be observed that the tip of cutting member (396) is extendable past the tip of carrier (394). This allows a cut to be made during each bit of the oscillatory travel of cutting blade (396).

Figure 15D shows, in cross-section, the relationship between carrier (394) and cutting blade (396). The cutting surface (398) is also depicted in this cross-sectional view.

The tissue mass removed by this curved blade is obviously not a cylindrical section as that term is used with respect to the devices and variations found above. The section or mass removed by this variation of the invention is respectively concave at one end and convex at the other. Nevertheless, other shapes that are deployable in this fashion are also contemplated.

Figure 16 shows a version of the invention (400) which the axial cutting members (402) and the radial cutting member (404) are moving as by rotating. Shaft (406) contains a small drive cable that engages a hub on the rotating blades (402) and (404).

Figure 17A depicts a tissue cutting member (410) having a straightforward radial cutting blade (412) and an axial cutting blade (414). The variation depicted in Figure 17 may be oscillated to enhance its cutting capabilities or may be imbued with RF or ultrasound energy as well. Figure 17B shows a cross-section of the device shown in Figure 17A. The angle (α) of cutting blade (415) as mounted on shaft (417)may range in value from 90° to 165° or so depending upon physical considerations such as, e.g., the size of the large lumen in the tissue removal member -- the smaller the lumen, the thinner the tissue spiral should be, the smaller the angle (α) should be.

Figures 18A and 18B show a variation of the cutting member (416) which includes a double-bladed cutting surface on both the axial cutting member (418) and the radial cutting member (420). This variation, the details of the cross-section of which are better depicted in Figure 18B, has a leading cutting surface (422) and a trailing cutting surface (424). They are separated by a modest gap (426).

TISSUE MANIPULATION DEVICES

Figures 19A through 19C show tissue manipulation devices as may be used in conjunction with the overall assembly. In some instances, it may be desirable to grasp the initial portion of excised tissue so to guide it through the tissue removal member. Depending on which of the configurations of tissue removal member is selected, a choice of one of the noted devices may be appropriate.

Figure 19A shows a simple endoscopic grasping device (500) that is readily available on the commercial market. Movement of the scissors-like handle produces a corresponding movement on the grasping tongs (504).

Figure 19B shows a tissue manipulation device (506) having a small wire-like shaft (508) and a harpoon-like end (510). For the purposes of completeness only, a manipulation knob (512) is also included for view. This picklike variation (506) is significantly flexible and may be used in, e.g., the auger tissue removal devices described above to ensure that the tissue in fact engages the interior of the auger and is removed as the auger turns.

Figure 19C shows a combination of braided grasper (520) and a hook component (522). The braided tissue snaring device (520) includes a distal woven braid section (524) that is easily manipulated by the two control wires or rods (526) and (528). If necessary, hook (522) is used to pull the excised tissue into braided cage (524). The two control wires (526) and (528) are used to either expand the diameter of braided cage (524) or to make that diameter smaller. Once the tissue is at least partially within the braided cage (524), the device is removed from the lumen of the tissue removal device.

Other devices for removing excised tissue from the selected site would certainly be appropriate. For example, suction may be applied through the large lumen alone or in conjunction with another tissue-removal device. Furthermore, a vacuum may be applied through a separate suction tool placed through the large lumen.

PROCEDURE FOR USE

Figures 20A through 20G show a generic method for using the tissue removal assembly of this invention. For the purposes of description here, this description assumes that the user is removing a lesion found in breast tissue. The lesion (600) is found behind skin surface (602), and has been marked with a localization wire (900). Surrounding tissue is also shown. The generic device found in Figure 1 is used for purposes of this

description. The use, however, according to this invention is not significantly different when other variations of the device are used.

Figure 20A shows the assembled device ready for introduction to the skin surface. Shown is the tissue removal member (100) and trocar (200) with the nestled cutting member (300) residing in the transverse slot found in trocar (200). Cutting member (300) preferably has a hollow shaft, which is placed over localization wire (900). The device is positioned at the skin surface so that when a complete rotation of the cutting member (300) is had, the lesion (600) is within that circumference.

Figure 20B shows the assembled device after it has penetrated the skin surface (602) and is approaching lesion (600).

Figure 20C shows the initial entry of the cutting member (300) into lesion (600). This variation shows the use of an RF powered cutting member (300). A mechanical or ultrasound cutter may obviously be employed as well or instead of an RF style cutter (300). The cutting member (300) is first rotated so to form a circular cut proximal of lesion (600). This circular cut will form the proximal end of the cylinder of tissue that is ultimately removed. As shown, the lumen of cutting member (300) is sized to accommodate the localization wire (900) and track it to the lesion (600). The cutting member (300) remains centered about the localization wire (900), ensuring that the cylinder of tissue ultimately removed contains the end of the localization wire, and therefore, the lesion (600). This represents a significant advantage over prior art devices that have large lumens that follow a localization wire, wherein the wire does not stay centered within the lumen. Furthermore, in these prior art devices, because the localization wire is not supported in the region to be cut, the compression of the tissue by the cutter may cause the wire to buckle. In the inventive device, the hollow shaft of the cutting member (300) supports the localization wire (900) from the outside and prevents it from buckling under compression.

Figure 20D then depicts the axial movement of the cutting member (300) and the spiral shape of the cut as the cutting member (300) is rotated until the radial portion (302) is past lesion (600).

Figure 20E shows the introduction of grasping member (500) to the proximal end of the cylindrical tissue mass (602) containing lesion (600).

Figure 20F shows the removal of the helically cut tissue of cylindrical tissue mass (602) through the large lumen of tissue removal of member (100). Tissue removal may be

accomplished using the grasping member (500) or using suction applied through the large lumen, or the combination of both grasping and suction. The localization wire (900), if used, may be removed along with the tissue, and may, in fact, aid in removing the tissue. The large lumen may be used to pack the remaining cavity with, e.g., inert packing material such as carbon.

Figure 20G shows the removal of tissue removal member (100) from the breast.

Figures 21A through 21H show an alternative method for using the tissue removal assembly of this invention. As before, the lesion (600) is found behind skin surface (602), and has been marked with a localization wire (900). However, in this case, smaller lumen member (106), which carries a deployable cutting member (300), can translate with respect to larger lumen member (104).

Figure 21A shows a tissue removal member (100) and trocar (200) with a deployable cutting member (300) protruding out of the smaller lumen (105) of smaller lumen member (106). Cutting member (300) has a hollow shaft, which is ready to be installed over localization wire (900).

Figure 21B shows the tissue removal assembly with localization wire (900) partially inserted into the hollow shaft of cutting member (300).

Figure 21C shows the assembled device ready for introduction to the skin surface (602). The cutting surface of deployable cutting member (300) has been straightened and inserted into the smaller lumen (105) of smaller lumen member (106). The distal end of localization wire (900) is partially within the hollow shaft of cutting member (300), which is within smaller lumen member (106).

Figure 21D shows the assembled device after it has penetrated the skin surface (602) and is approaching lesion (600).

Figure 21E shows smaller lumen member (106) penetrating lesion (600) and continuing until it is just past the lesion. Smaller lumen member (106) has a slightly tapered or conical shaped distal end (107) to aid in penetrating the tissue. Cutting member (300) is still residing (hidden) within smaller lumen member (106).

Figure 21F shows the distal end of cutting member (300) emerging from smaller lumen member (106) and deployed to take on a squared-J shape distal of lesion (600). This may be done by pushing the cutting member (300) out of smaller lumen member (106) or by slightly retracting smaller lumen member (106), or both. Although not shown, it should

be noted that if smaller lumen member (106) is be retracted slightly to aid in deploying cutting member (300), member (106) may then be pushed slightly forward again following cutting member deployment to aid in supporting the cutting member during cutting.

Figure 21G shows the initial cut of the cutting member (300) distal of lesion (600). The cutting member (300) is first rotated so to form a circular cut (604) distal of lesion (600). This circular cut will form the distal end of the cylinder of tissue that is ultimately removed.

Figure 21H then depicts the axial movement of the cutting member (300) and smaller lumen member (106), and the spiral shape of the cut as the cutting member (300) is rotated until the radial portion (802) is proximal of lesion (600). It should be noted that once cutting member (300) is deployed distal of lesion (600), smaller lumen member (106) may be fully retracted to its initial position; alternatively, once cutting member (300) is deployed, smaller lumen member (106) may be retracted as cutting member (300) is retracted. Once the cutter has reached the most proximal portion to be cut, axial movement is stopped long enough to make a radial cut to sever the proximal end of the sample. The cutting member (300) may optionally be retracted back into smaller lumen member (106).

One advantage of the method shown in Figures 21A-21H and described herein is that the cutting action occurs while pulling cutting member (300) toward the physician instead of while pushing it into the tissue.

Following the spiral cut, tissue is removed as previously described. In procedures that use a localization wire, such as those described with respect to Figures 20A-20G and 21A-21H, the localization wire may be straight or may have a "J" or other shape on its distal end. This shaped or angled distal end may be straightened so that it may enter the shaft of the cutting member. Alternatively, the distal end of the localization wire may be placed slightly distal of lesion (600), and the discrete tissue mass may be excised from a position slightly proximal of the localization wire distal end. In that case, the localization wire distal end (e.g., the "J"-shaped portion) never has to enter the cutting member hollow shaft.

The invention herein has been described by examples and a particularly desired way of practicing the invention has been described. However, the invention as claimed herein is not loaded to that specific description in any manner. Equivalence to the description as hereinafter claimed is considered to be within the scope of protection of this patent.

WE CLAIM AS OUR INVENTION:

1. A tissue removal assembly having a proximal end and a distal end, comprising:

a.) a tubular tissue removal member having a wall, a distal diameter, a proximal end, a distal end, and a longitudinal axis extending between said proximal end and said distal end; an open, distally located tissue entry opening; a relatively more proximal, tissue exit port; and a tissue removal passageway extending between said tissue entry opening and said tissue exit port;

b.) a cutting member, rotatable with respect to said tubular tissue removal member in a diameter greater than the tubular tissue removal member distal diameter, extendible beyond said distally located tissue entry opening, and having a cutting surface, where upon rotation of said cutting member and extension of said cutting member distally beyond said tissue entry opening within a tissue region, said cutting surface cuts a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal member axis which is greater than said tubular tissue removal member distal diameter and which discrete tissue mass is in a configuration removable through said tissue entry opening.

2. The tissue removal assembly of claim 1 wherein said cutting surface is configured to cut a radial, helical path through discrete tissue mass.

3. The tissue removal assembly of claim 1 wherein said cutting member is manually manipulatable from the proximal end of said tubular tissue removal member.

4. The tissue removal assembly of claim 1 wherein said cutting member has a generally rounded "J" shape.

5. The tissue removal assembly of claim 1 wherein said cutting member has a generally squared "J" shape.

6. The tissue removal assembly of claim 1 wherein said cutting member has an "L"

shape.

7. The tissue removal assembly of claim 1 wherein said cutting member has an axis of rotation and a distal extension along said axis of rotation.

8. The tissue removal assembly of claim 1 wherein said cutting member is at least partially radio-opaque.

9. The tissue removal assembly of claim 7 wherein said cutting member is at least partially radio-opaque.

10. The tissue removal assembly of claim 7 wherein said cutting member distal extension is at least partially radio-opaque.

11. The tissue removal assembly of claim 1 wherein said cutting member is a wire cutting member.

12. The tissue removal assembly of claim 1 wherein said cutting member is a ribbon cutting member.

13. The tissue removal assembly of claim 1 wherein said cutting member comprises a material selected from the group consisting of titanium, nickel, stainless steel, cobalt, tantalum, and mixtures and alloys thereof.

14. The tissue removal assembly of claim 1 wherein said cutting member comprises titanium and nickel.

15. The tissue removal assembly of claim 1 wherein said cutting member is an RF cutter utilizing radio-frequency energy to cut said discrete tissue mass.

16. The tissue removal assembly of claim 15 further comprising an RF source connected to said cutting member which is suitable for cutting said discrete tissue mass.

17. The tissue removal assembly of claim 1 wherein said cutting member is a mechanical blade.

18. The tissue removal assembly of claim 17 wherein said mechanical blade cutting member is vibrated.

19. The tissue removal assembly of claim 1 wherein said cutting member is an RF cutter having a sharp mechanical cutting surface.

20. The tissue removal assembly of claim 1 wherein said cutting member is an ultrasound cutter utilizing high frequency audio energy to cut said discrete tissue mass.

21. The tissue removal assembly of claim 20 further comprising an ultrasound source connected to said cutting member which is suitable for cutting said discrete tissue mass.

22. The tissue removal assembly of claim 1 wherein said tubular tissue removal member further includes a shaft passageway generally parallel to said tubular tissue removal member longitudinal axis and said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and is slideable within and rotatable within said shaft passageway to advance said cutting surface.

23. The tissue removal assembly of claim 1 wherein said tubular tissue removal member further includes a shaft passageway interior to said tissue removal passageway and generally parallel to said tubular tissue removal member longitudinal axis and said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and is slideable within and rotatable within said shaft passageway to advance said cutting surface.

24. The tissue removal assembly of claim 1 further comprising a pick locatable within said

tissue removal passageway which pick is configured for removing said discrete tissue mass.

25. The tissue removal assembly of claim 1 further comprising a manipulatable grasping tool locatable within said tissue removal passageway which grasping tool is configured for removing said discrete tissue mass.

26. The tissue removal assembly of claim 25 wherein said manipulatable grasping tool comprises a pair of opposing jaws suitable for grasping said discrete tissue mass.

27. The tissue removal assembly of claim 25 wherein said manipulatable grasping tool comprises a grasping braid suitable for grasping said discrete tissue mass.

28. The tissue removal assembly of claim 1 further comprising a manipulatable suction tool locatable within said tissue removal passageway which suction tool is configured for removing said discrete tissue mass.

29. The tissue removal assembly of claim 1 further comprising a trocar sized to fit within said tissue removal passageway.

30. The tissue removal assembly of claim 29 wherein said trocar includes a slot and said cutting surface fits in said trocar slot.

31. The tissue removal assembly of claim 29 wherein said trocar is extendible distally though said tissue entry opening.

32. The tissue removal assembly of claim 1 wherein said tissue entry opening is open along the axis of said tubular tissue removal member.

33. The tissue removal assembly of claim 1 wherein said tissue entry opening is open generally perpendicular to the axis of said tubular tissue removal member.

34. The tissue removal assembly of claim 1 further comprising a rotatable auger situated within said tubular tissue removal member for moving excised tissue along said tubular tissue removal member to said tissue exit port.

35. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

introducing a tissue removal assembly to a region adjacent a selected internal tissue region, said tissue removal assembly comprising:

a.) a tubular tissue removal member having a wall, a distal diameter, a proximal end, a distal end and a longitudinal axis extending between said proximal end and said distal end; an open, distally located tissue entry opening; a relatively more proximal, tissue exit port; and a tissue removal passageway extending between said tissue entry opening and said tissue exit port,

b.) a cutting member, rotatable with respect to said tubular tissue removal member in a diameter greater than the tubular tissue removal member distal diameter, extendible beyond said distally located tissue entry opening, and having a cutting surface, where upon rotation of said cutting member and extension of said cutting member distally beyond said tissue entry opening within said tissue region, said cutting surface cuts a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal member axis which is greater than said tubular tissue removal member distal diameter and which discrete tissue mass is in a configuration removable through said tissue entry opening,

rotating said cutting member and said cutting surface to form a discrete tissue mass having an overall diameter measured generally orthogonal to the tubular tissue removal member axis which is greater than said tubular tissue removal member distal diameter and which discrete tissue mass is in a configuration removable through said tissue entry opening, and

removing said discrete tissue mass through said tissue entry opening, through said tissue removal passageway, and out through said tissue exit port.

36. The procedure of claim 35 wherein the cutting member is rotated to form a helical cut in said discrete tissue mass.

37. The procedure of claim 35 wherein said cutting member has a generally rounded "J" shape.

38. The procedure of claim 35 wherein said cutting member has a generally squared "J" shape.

39. The procedure of claim 35 wherein said cutting member has an "L" shape.

40. The procedure of claim 35 wherein said cutting member has an axis of rotation and a distal extension along said axis of rotation.

41. The procedure of claim 35 wherein said cutting member is at least partially radio-opaque.

42. The procedure of claim 35 wherein said cutting member is a wire cutting member.

43. The procedure of claim 35 wherein said cutting member comprises a material selected from the group consisting of titanium, nickel, stainless steel, cobalt, tantalum, and mixtures and alloys thereof.

44. The procedure of claim 43 wherein said cutting member comprises titanium and nickel.

45. The procedure of claim 35 wherein said cutting member is an RF cutter utilizing radio-frequency energy to cut said discrete tissue mass and wherein said step of rotating said

cutting member and said cutting surface to form a discrete tissue mass includes the imposition of radio-frequency energy to effectuate said cutting.

46. The procedure of claim 35 wherein said cutting member is a mechanical blade.

47. The procedure of claim 46 wherein said mechanical blade cutting member is vibrated.

48. The procedure of claim 35 wherein said cutting member is an RF cutter having a sharp mechanical cutting surface.

49. The procedure of claim 35 wherein said cutting member is an ultrasound cutter utilizing high frequency audio energy to cut said discrete tissue mass and further including the step of applying ultrasound energy to said cutting member.

50. The procedure of claim 35 wherein said trocar includes a slot and said cutting surface fits in said trocar slot.

51. The procedure of claim 35 wherein said tissue removal assembly further comprises a rotatable auger situated within said tubular tissue removal member for moving excised tissue along said tubular tissue removal member to said tissue exit port and wherein said procedure includes rotating said auger to remove excised tissue.

52. The procedure of claim 51 further comprising the step of reconstituting the excised tissue to the form as found prior to the cutting step.

53. A procedure for removing tissue from a selected internal tissue region, comprising the steps of:

introducing, to a position adjacent a selected internal tissue region, a tissue removal member and a cutting member rotatable with respect to said tubular tissue removal member,

rotating and translating said cutting member to form a helically cut discrete tissue mass in said selected internal tissue region having a diameter generally greater than said

tissue removal member, and

removing said discrete tissue mass through said tissue removal member.

54. The procedure of claim 53 including the step of introducing RF energy to said cutting member to form said helical cut in said discrete tissue mass.

55. The procedure of claim 53 wherein said cutting member is a mechanical blade.

56. The procedure of claim 53 further including the step of vibrating said mechanical blade cutting member.

57. The procedure of claim 53 further including the step of moving excised tissue along said tubular tissue removal member using a rotatable auger situated within said removal member by rotating said auger.

58. The procedure of claim 57 further comprising the step of reconstituting the excised tissue to the form as found prior to the cutting step.

59. The procedure of claim 53 wherein the cutting member comprises a hollow shaft, and wherein said introducing step further comprises introducing the hollow shaft over a distal end of a localization wire having a distal end proximate the selected internal tissue region.

60. The procedure of claim 59 wherein said rotating and translating step further comprises rotating the cutting member about the localization wire and translating the cutting member along the localization wire.

61. The procedure of claim 59 and further including a step of removing the localization wire through the tissue removal member.

62. The procedure of claim 59 wherein said step of removing the localization wire occurs simultaneously with said step of removing the tissue.

63. A procedure for cutting tissue from a selected internal tissue region marked with a localization wire, comprising the steps of:

inserting a distal end of the localization wire into a hollow shaft of a cutting member, wherein the hollow shaft has an inner diameter approximately equal to the width of the localization wire;

translating the cutting member over the localization wire to the selected internal tissue region; and

cutting a discrete tissue mass in the selected internal tissue region.

64. The tissue removal assembly of claim 1 wherein said cutting member further includes a hollow shaft extending between said tissue removal assembly proximal end and said tissue removal assembly distal end, wherein said hollow shaft includes an open distal end.

65. The tissue removal assembly of claim 64 wherein said tubular tissue removal member further includes a shaft passageway generally parallel to said tubular tissue removal member longitudinal axis, wherein said cutting member shaft is slideable within and rotatable within said shaft passageway.

66. The tissue removal assembly of claim 65 wherein said shaft passageway is exterior to said tissue removal passageway.

67. The tissue removal assembly of claim 22 wherein said shaft passageway is exterior to said tubular tissue removal member.

68. The tissue removal assembly of any one of claims 22, 23, or 67, further comprising a small lumen member and wherein said shaft passageway is located within said small lumen member and wherein said small lumen member is movable with respect to said tubular tissue removal member.

69. The tissue removal assembly of claim 69 wherein said small lumen member has a

tapered distal end.

70. The tissue removal assembly of claim 68 or 69 wherein said cutting surface is deployable through said shaft passageway.

71. A procedure for preparing a tissue biopsy sample, comprising the steps of:

rotating a cutting member with respect to the tissue biopsy sample; and

simultaneously advancing the cutting member with respect to the tissue biopsy sample to helically cut the tissue biopsy sample.

72. The procedure of claim 53 wherein said introducing step comprises introducing the cutting member to a position proximal of the selected internal tissue region; and wherein said rotating and translating step includes:

rotating the cutting member to first form a circular cut proximal of said selected internal tissue region,

then advancing and rotating the cutting member through the selected internal tissue region to form a helically cut discrete tissue mass in the selected internal tissue region, and

then rotating the cutting member to form a circular cut distal of the selected internal tissue region.

73. The procedure of claim 53 wherein said introducing step comprises introducing the cutting member to a position distal of the selected internal tissue region; and wherein said rotating and translating step includes:

rotating the cutting member to first form a circular cut distal of the selected internal tissue region,

then pulling back and rotating the cutting member through the selected internal tissue region to form a helically cut discrete tissue mass in the selected internal tissue region, and

then rotating the cutting member to form a circular cut proximal of the selected internal tissue region.

74. The procedure of claim 53 wherein said step of removing the discrete tissue mass occurs simultaneously with said step of rotating and translating the cutting member.

75. The procedure of claim 53 wherein said step of removing the discrete tissue mass occurs after said step of rotating and translating the cutting member.

76. The tissue removal assembly of claim 1 wherein said cutting surface is serrated.

77. The tissue removal assembly of claim 1 wherein said cutting member includes a shaft extending between said cutting surface and said tubular tissue removal member proximal end and wherein at least a portion of said cutting surface is skew to said shaft.

78. The tissue removal assembly of claim 1 wherein, upon rotation and/or translation of said cutting member, said cutting surface follows a cutting path, and wherein said cutting surface is nonperpendicular to said cutting path.

79. The tissue removal assembly of claim 64 wherein said cutting member hollow shaft has an inner surface and wherein said inner surface is electrically and/or thermally insulated.

80. The tissue removal assembly of claim 64 further comprising a localization wire having a proximal end and a distal end, wherein said localization wire distal end is adapted for placement within said selected tissue and wherein said localization wire proximal end is adapted for placement within said cutting member hollow shaft, and wherein said localization wire is electrically and/or thermally insulated.

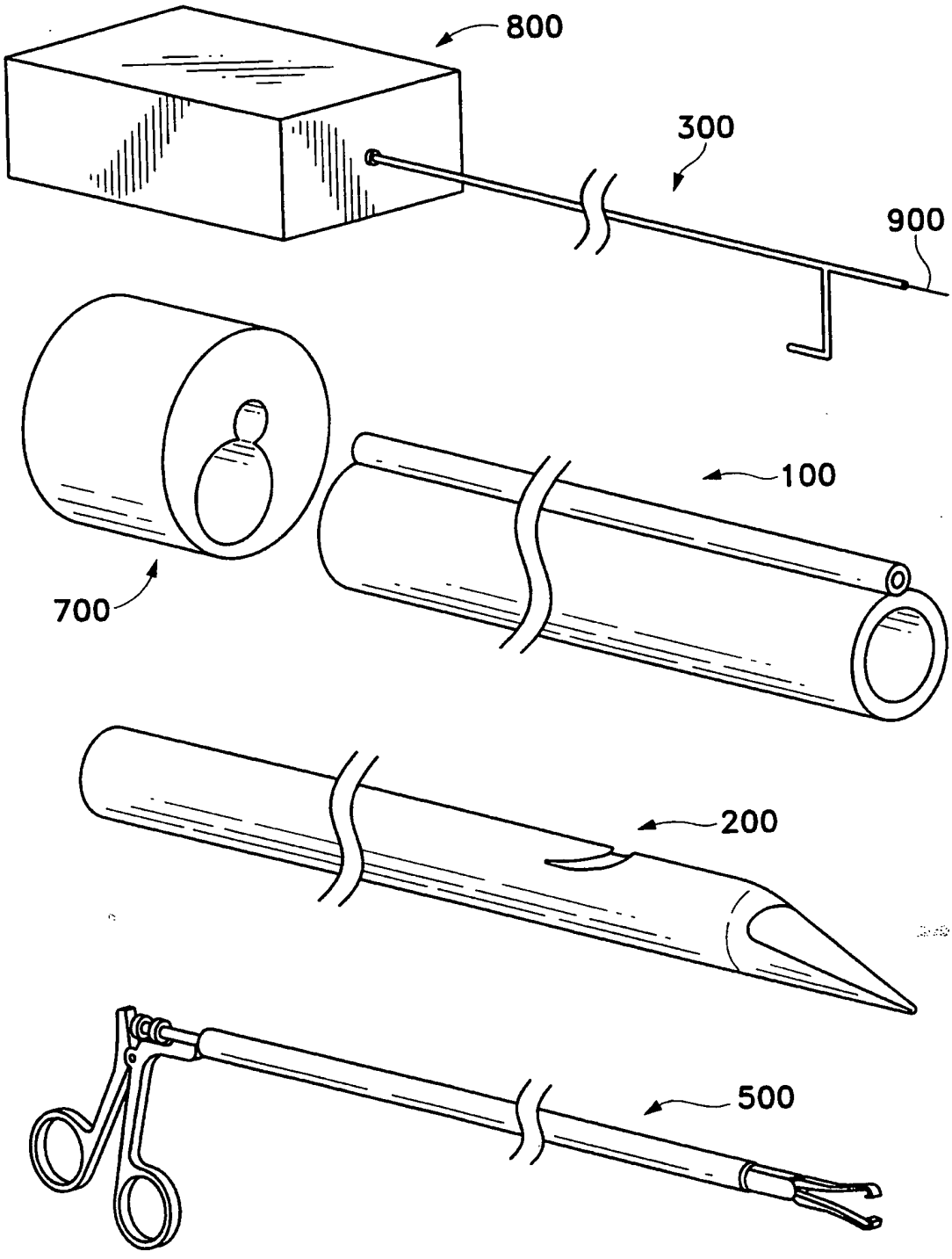


Fig. 1

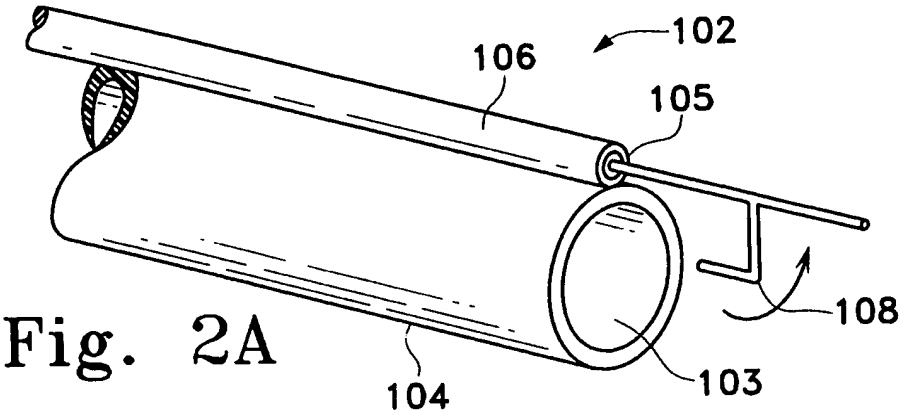


Fig. 2A

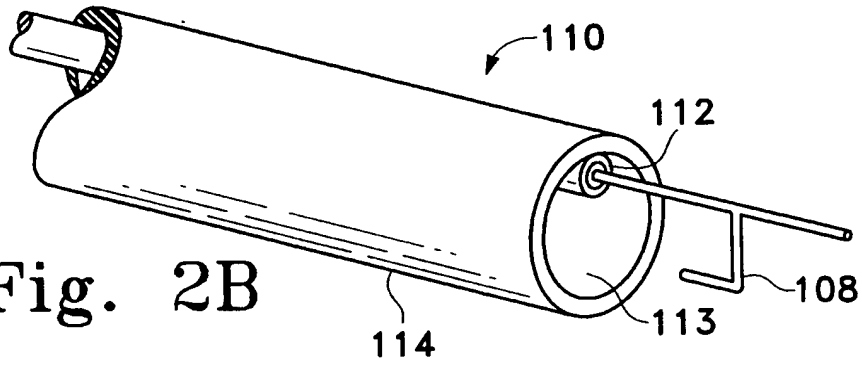


Fig. 2B

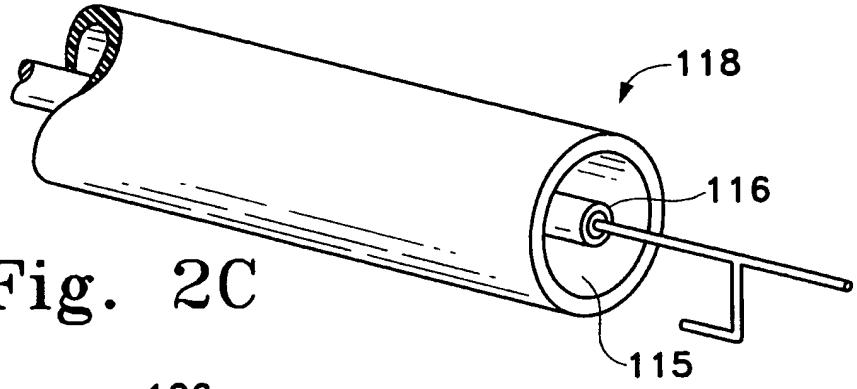


Fig. 2C

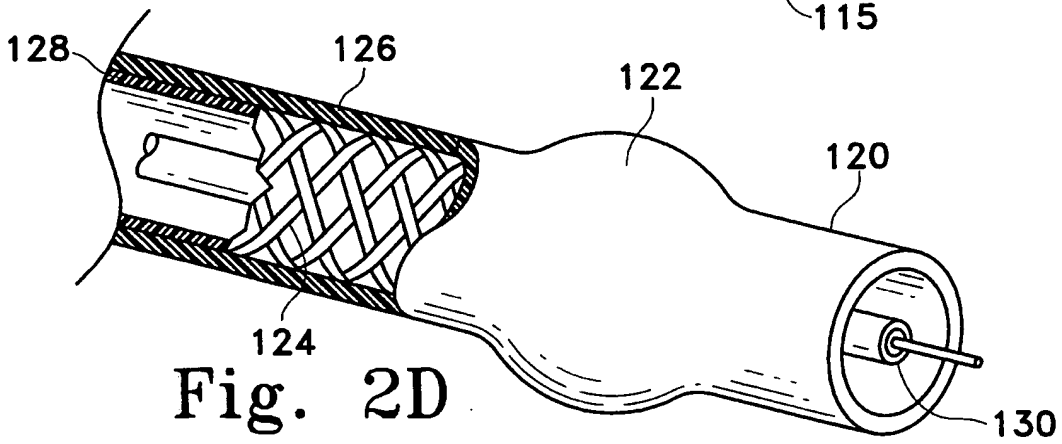


Fig. 2D

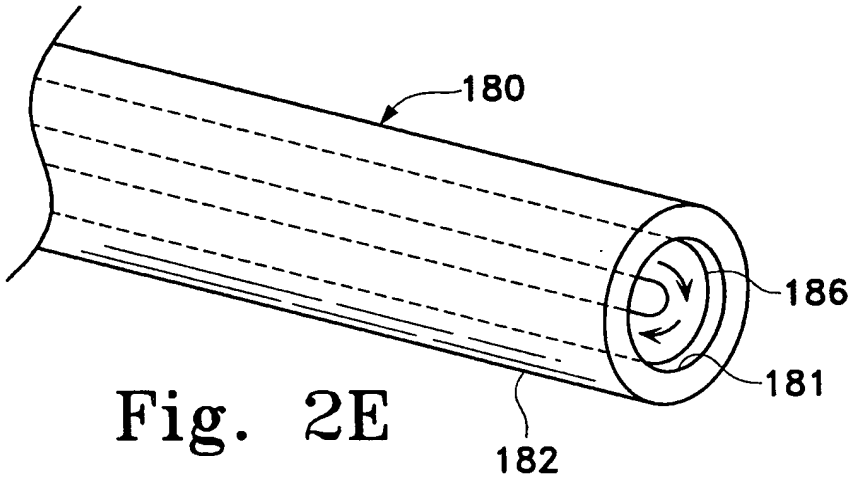


Fig. 2E

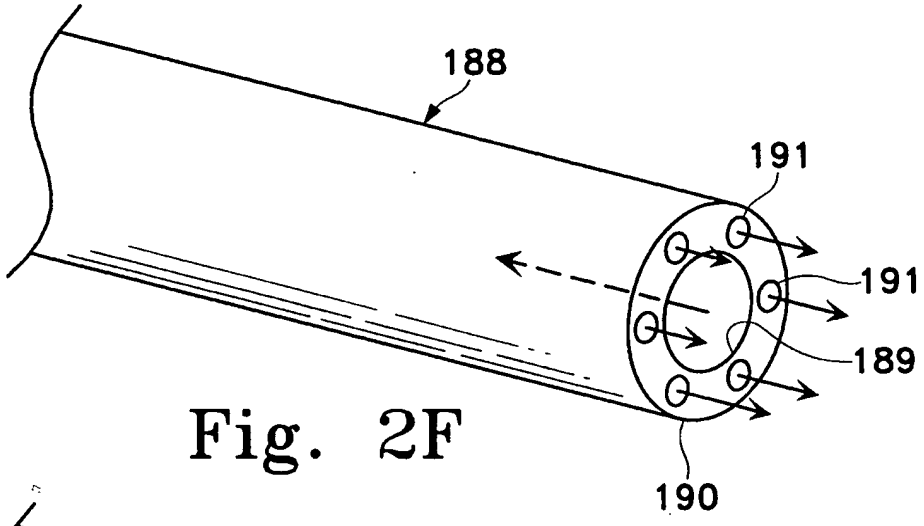


Fig. 2F

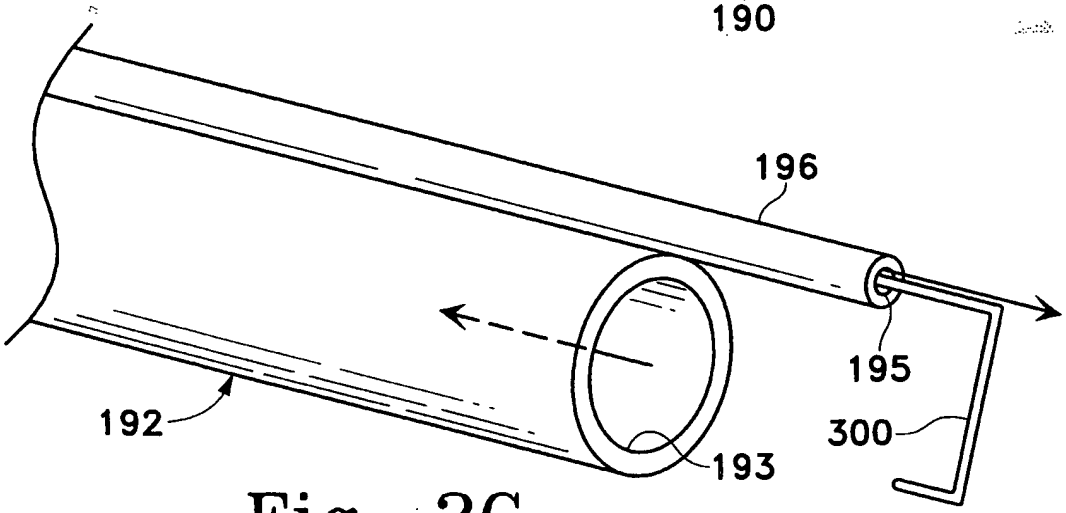


Fig. 2G

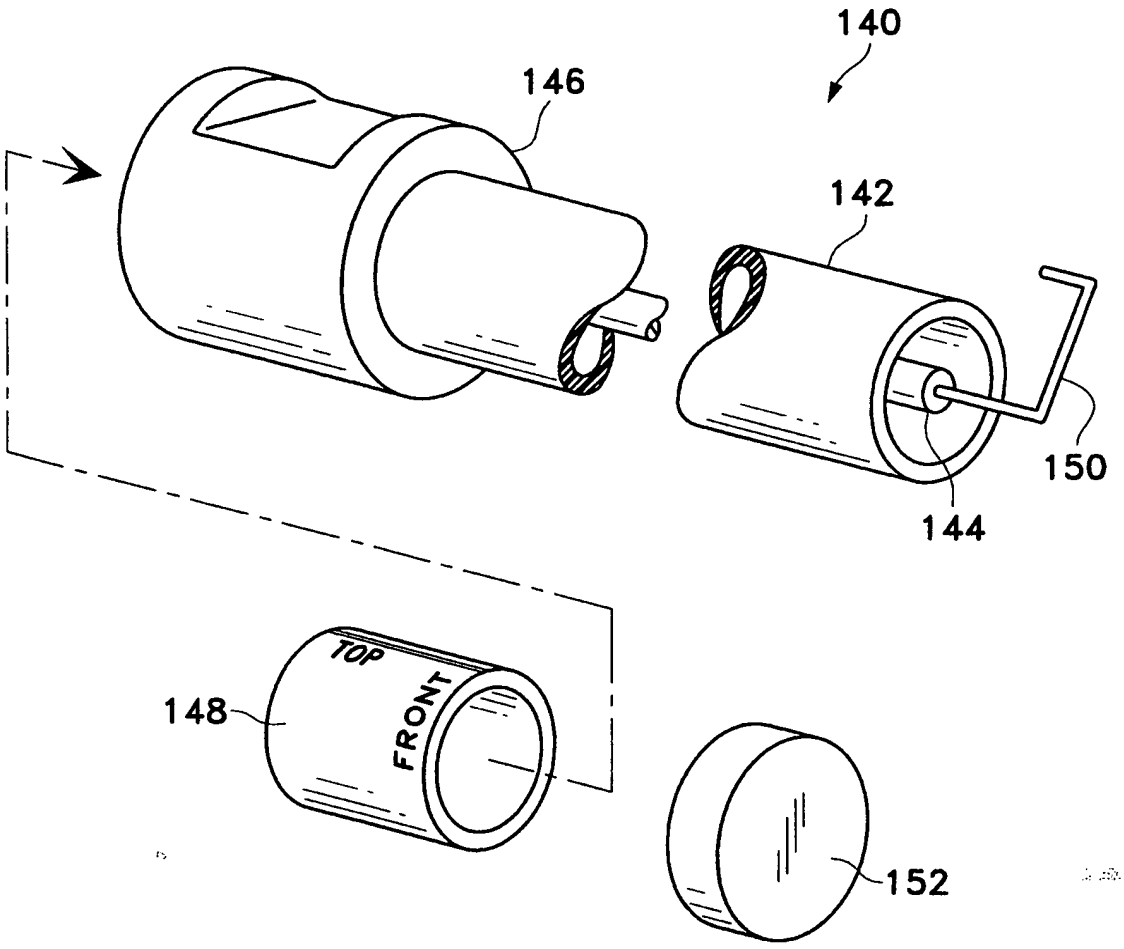


Fig. 3

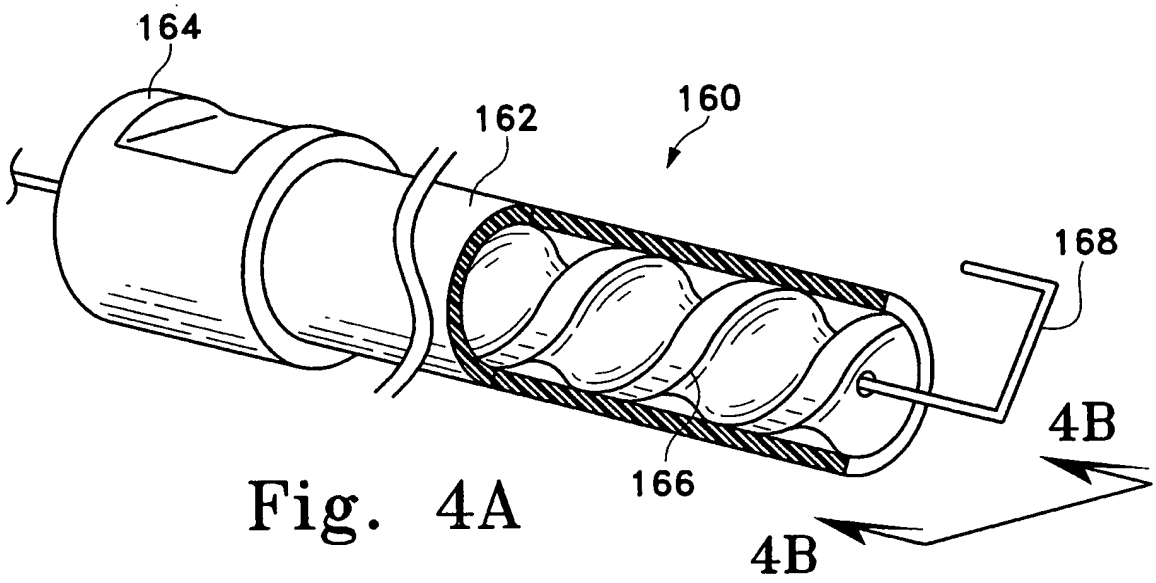


Fig. 4A

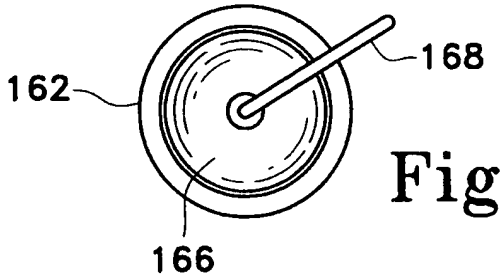


Fig. 4B

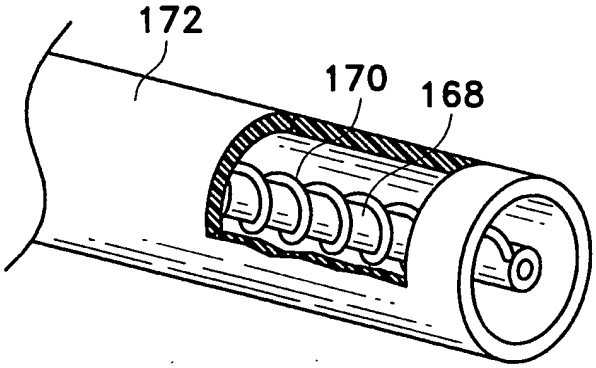


Fig. 5

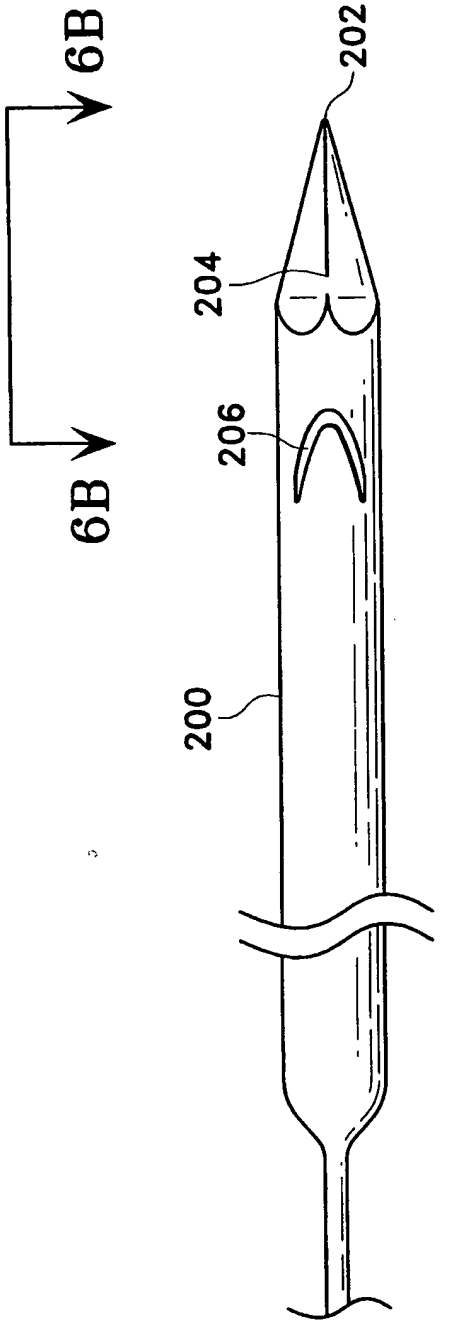


Fig. 6A

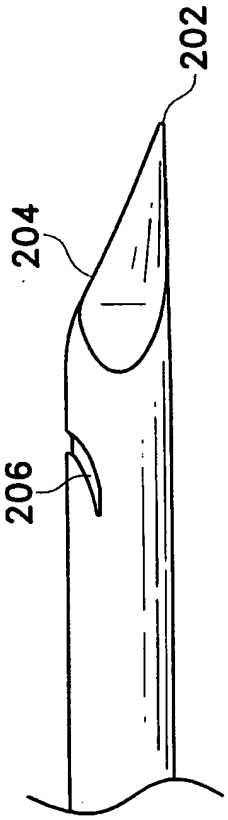


Fig. 6B

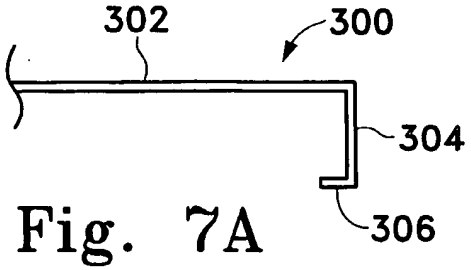


Fig. 7A

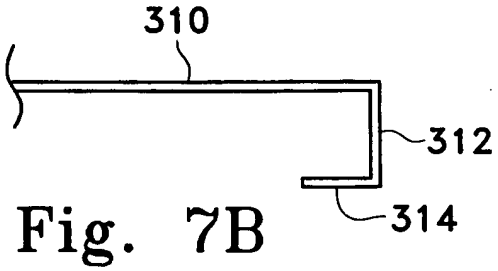


Fig. 7B

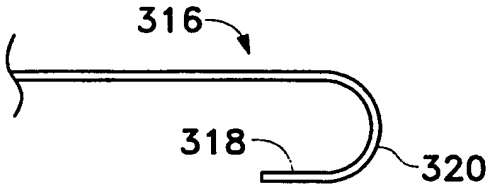


Fig. 7C

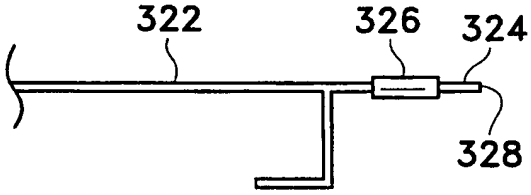


Fig. 7D

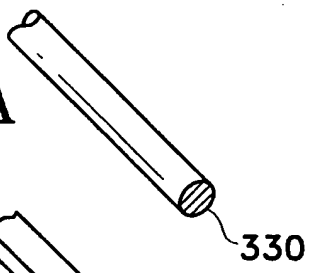


Fig. 8A

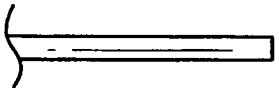


Fig. 8B

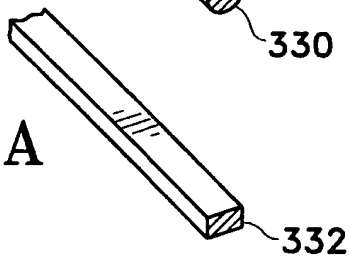


Fig. 9A

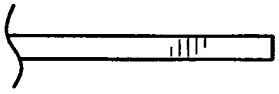


Fig. 9B

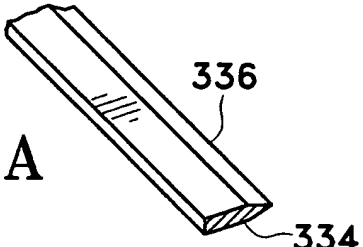


Fig. 10A

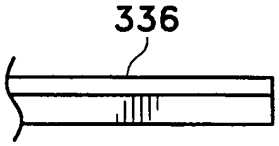


Fig. 10B

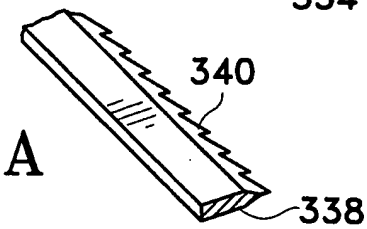


Fig. 11A

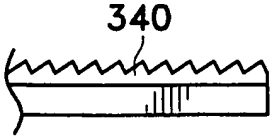


Fig. 11B

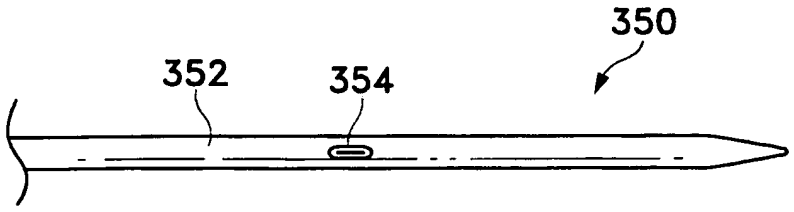


Fig. 12A

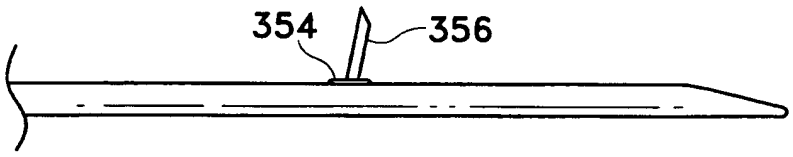


Fig. 12B

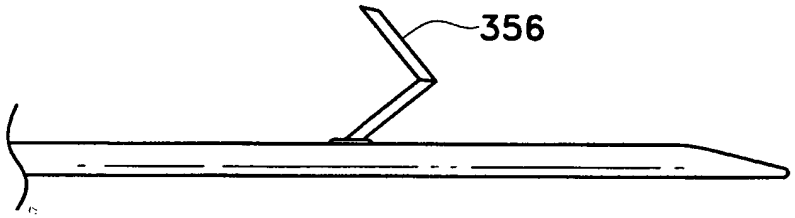


Fig. 12C

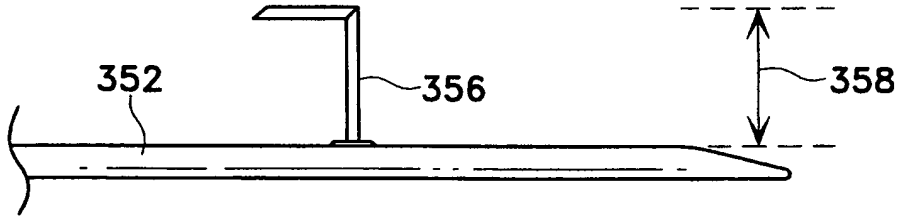


Fig. 12D

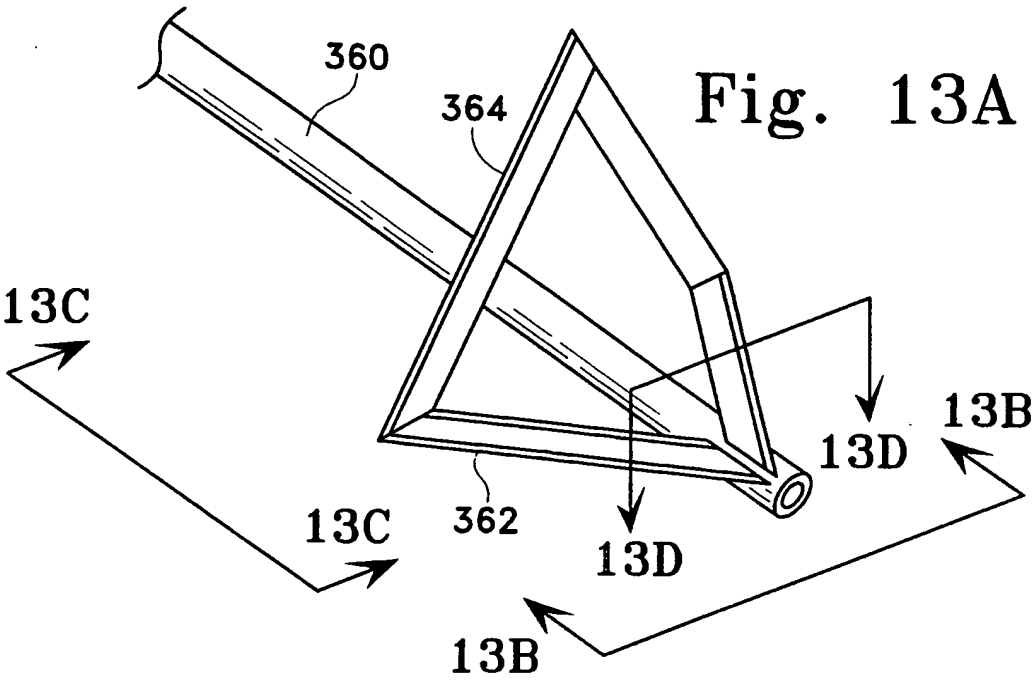


Fig. 13A

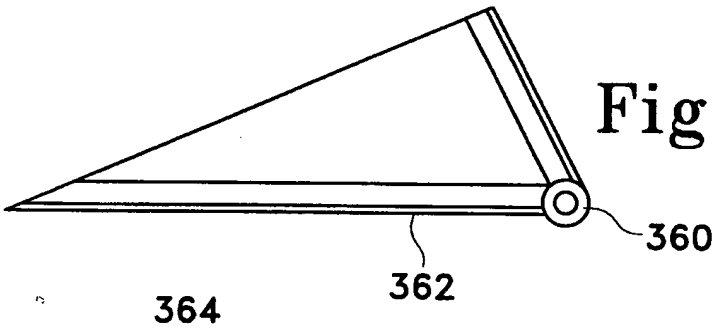


Fig. 13B

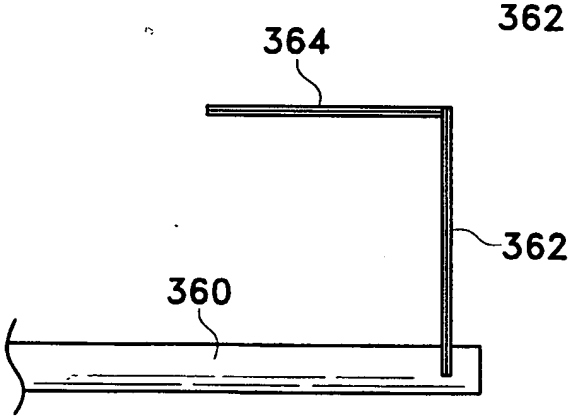


Fig. 13C

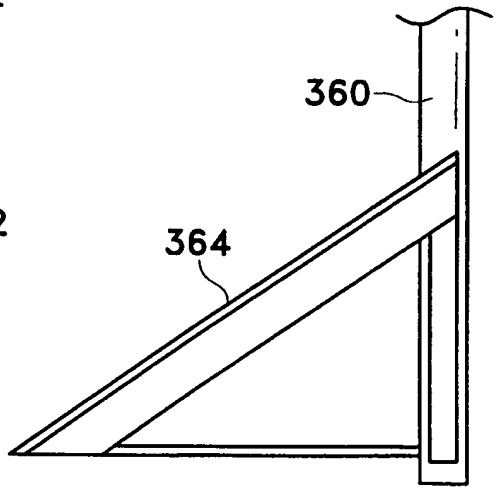


Fig. 13D

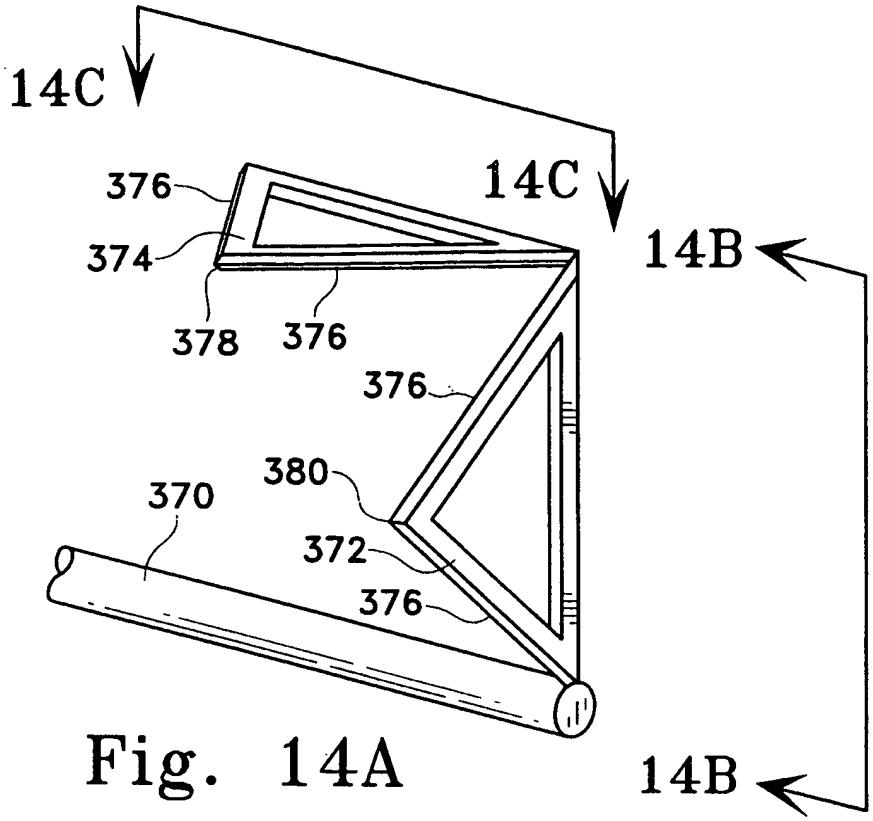


Fig. 14A

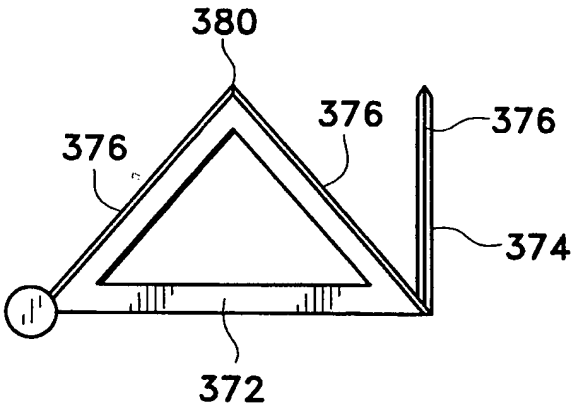


Fig. 14B

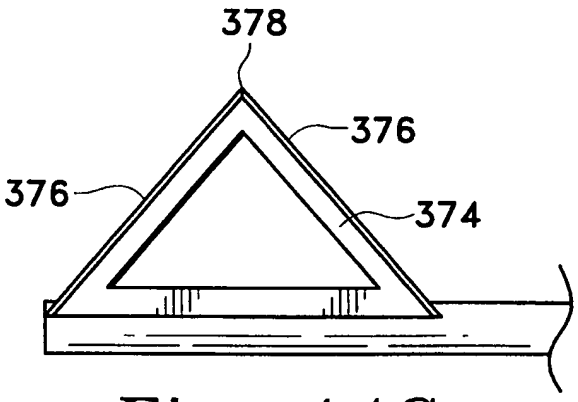


Fig. 14C

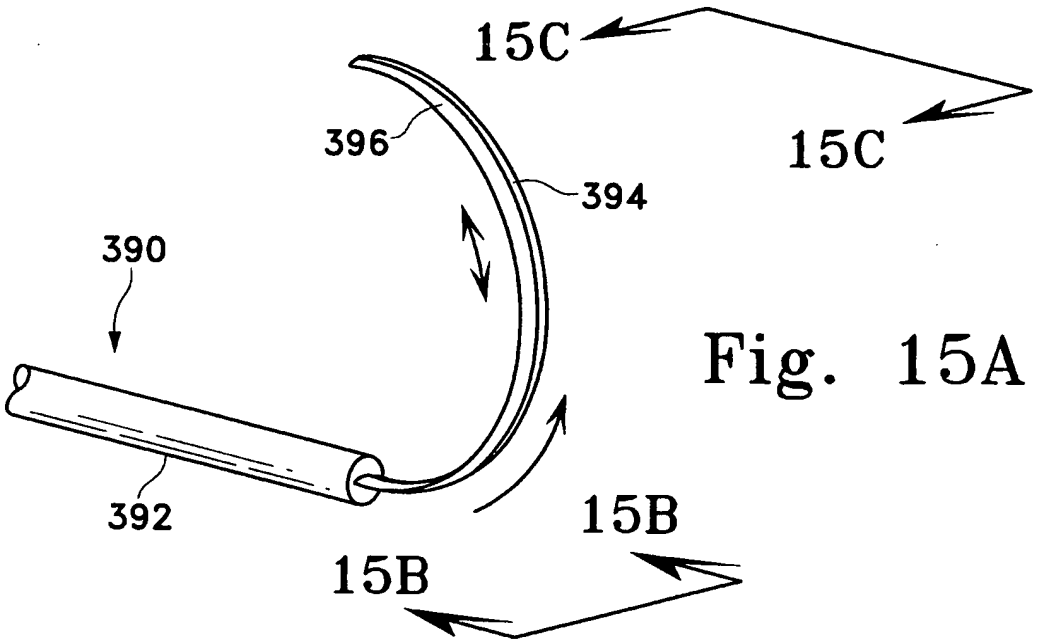


Fig. 15A

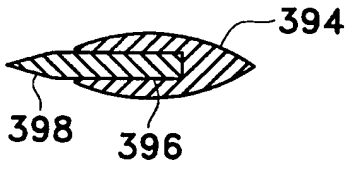


Fig. 15D

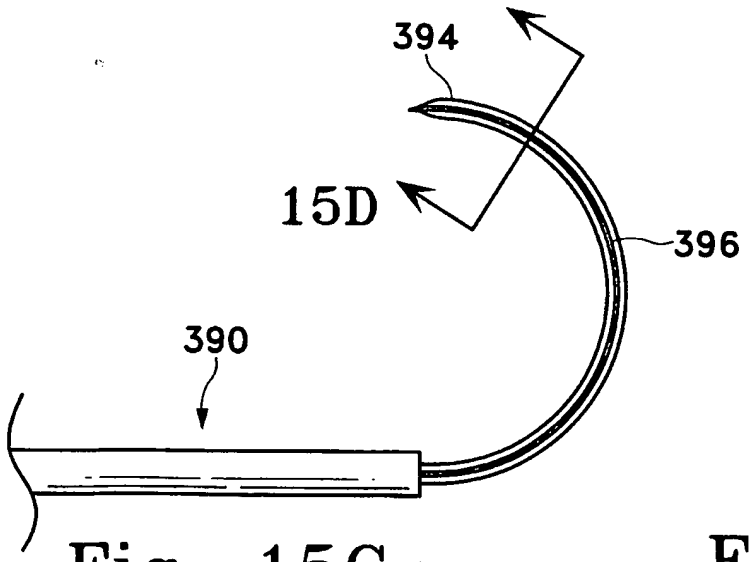


Fig. 15C

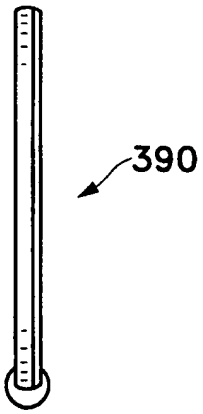
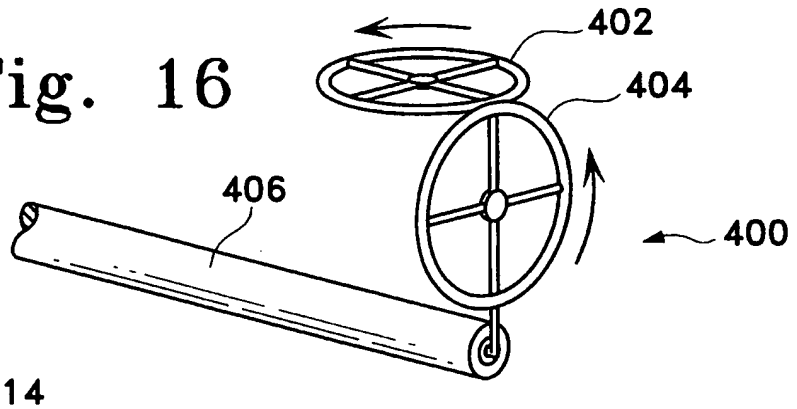


Fig. 15B

Fig. 16



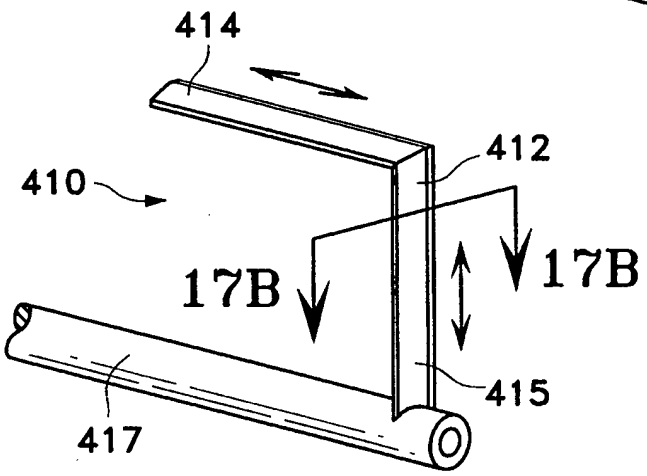


Fig. 17A

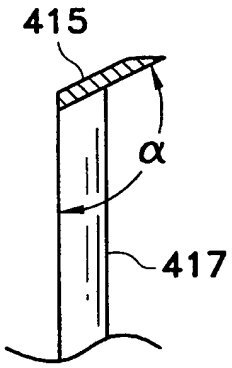


Fig. 17B

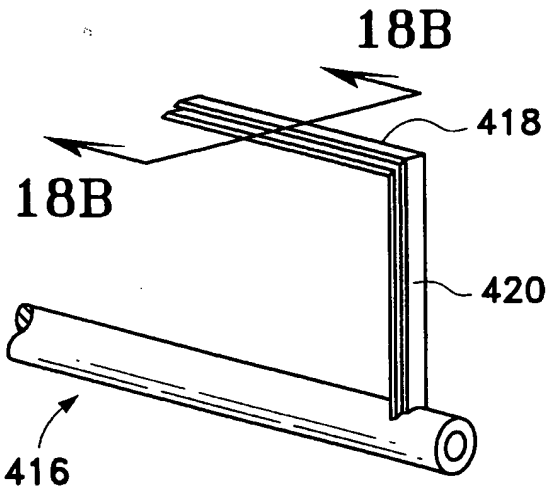


Fig. 18A

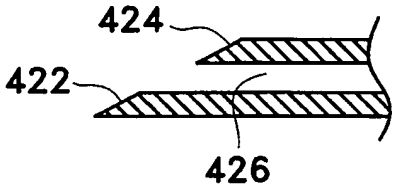


Fig. 18B

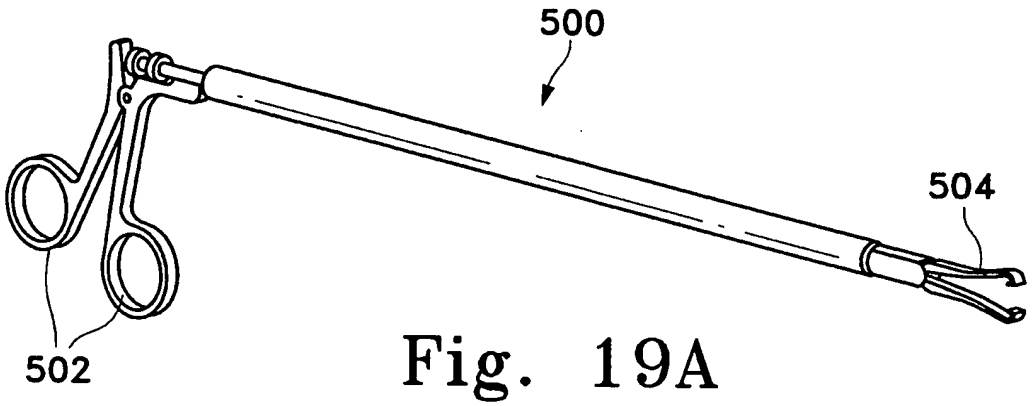


Fig. 19A

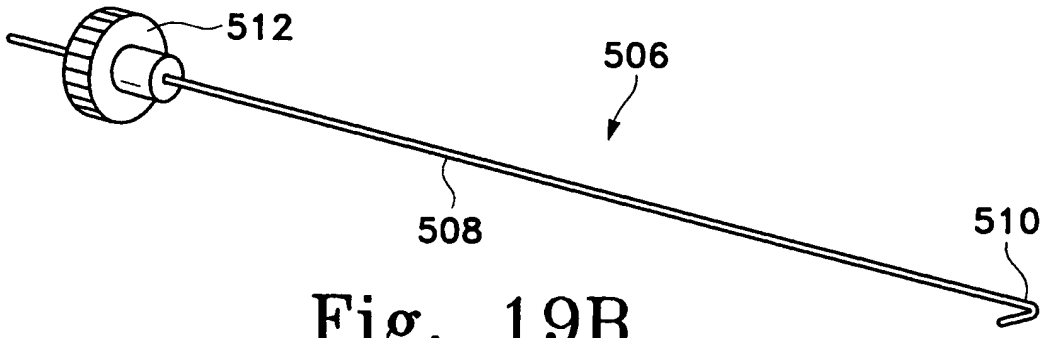


Fig. 19B

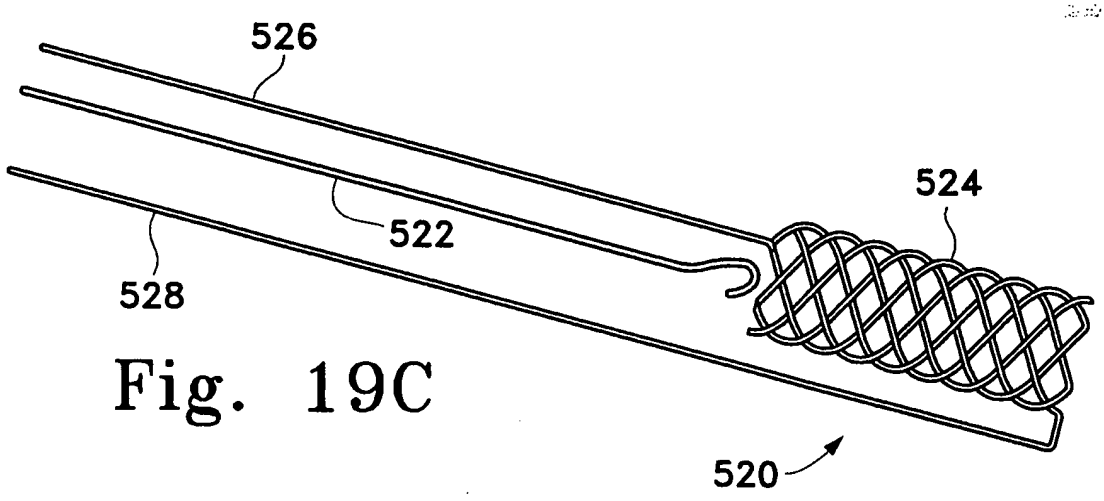


Fig. 19C

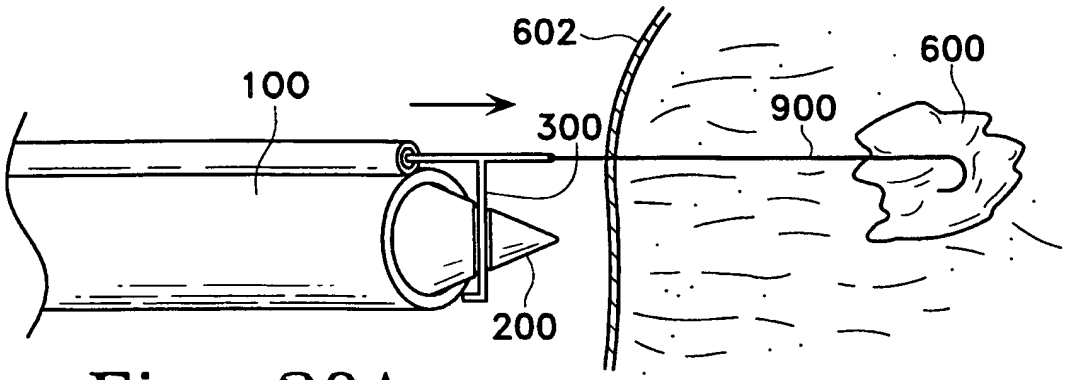


Fig. 20A

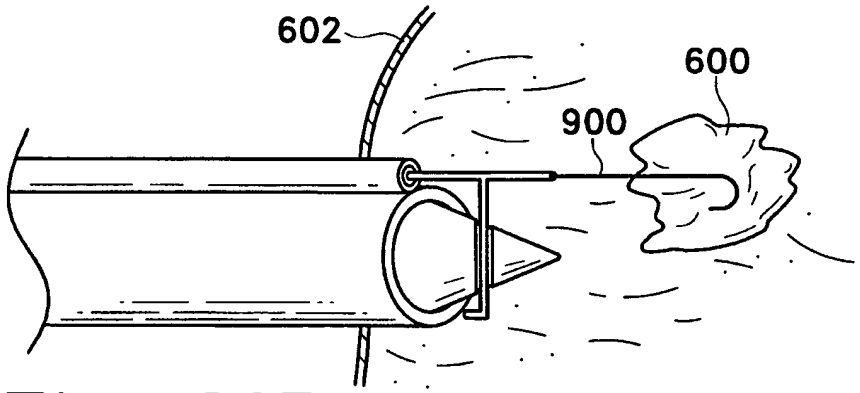


Fig. 20B

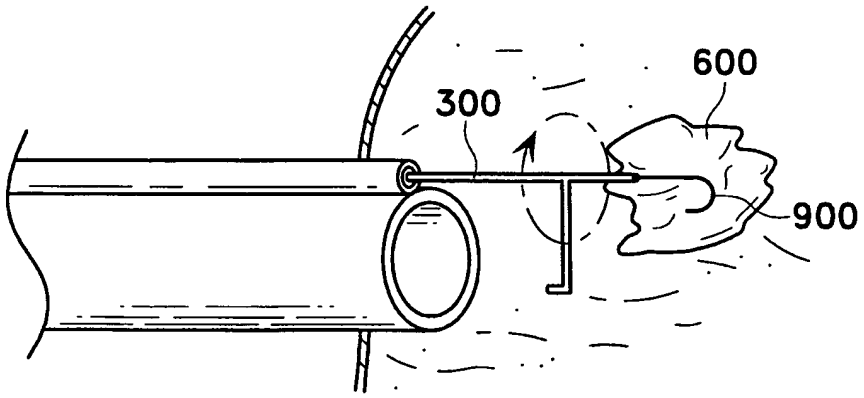


Fig. 20C

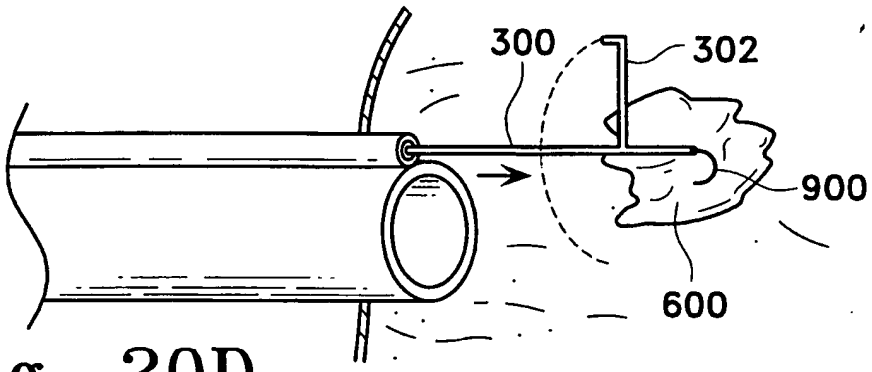


Fig. 20D

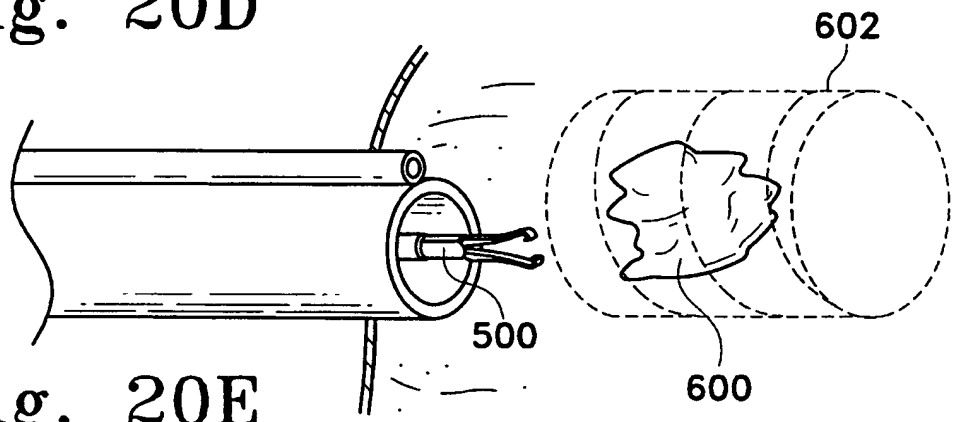


Fig. 20E

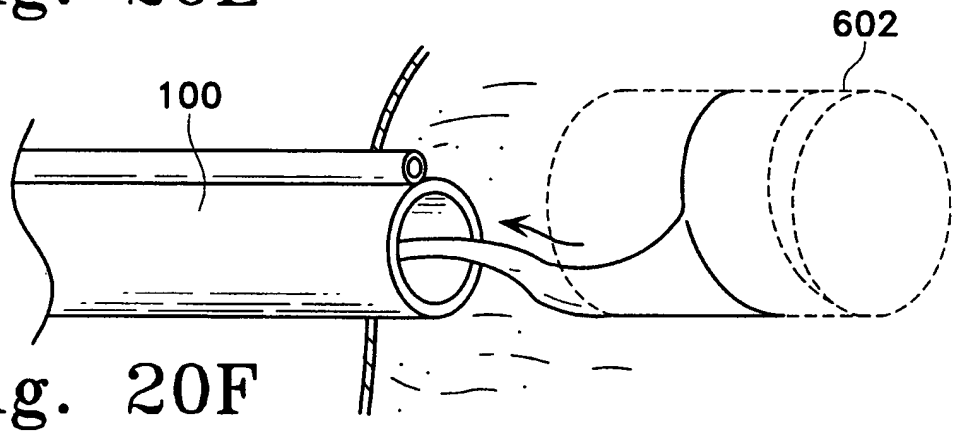


Fig. 20F

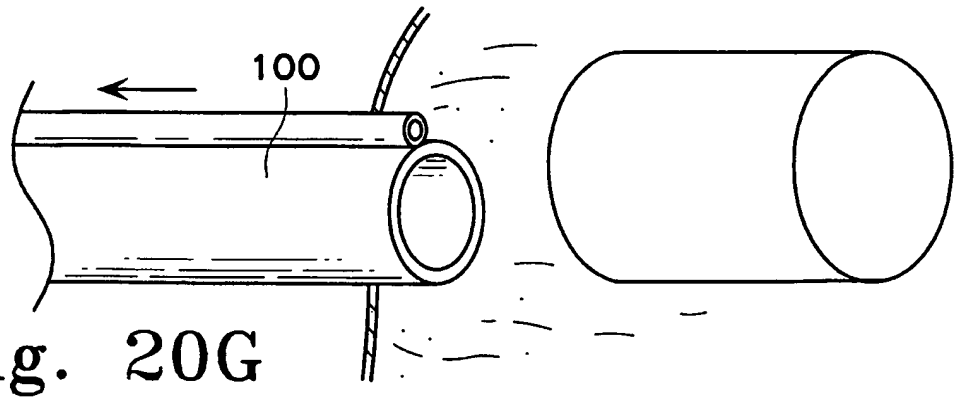


Fig. 20G

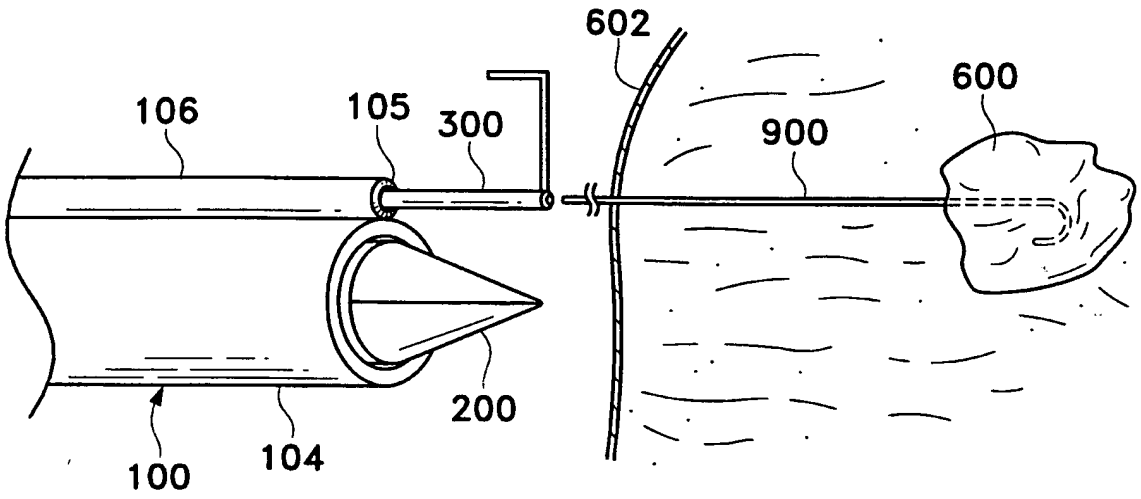


Fig. 21A

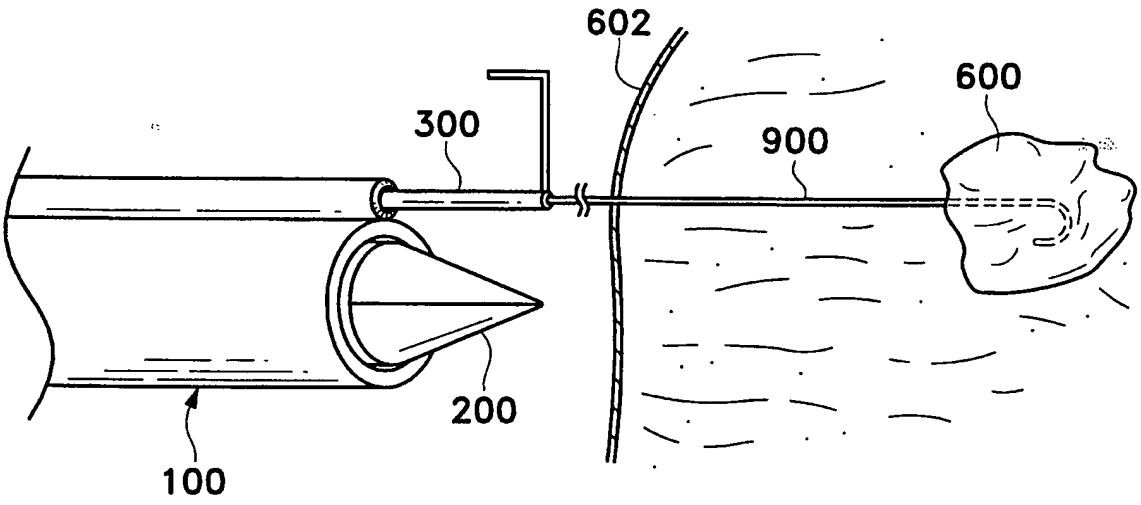


Fig. 21B

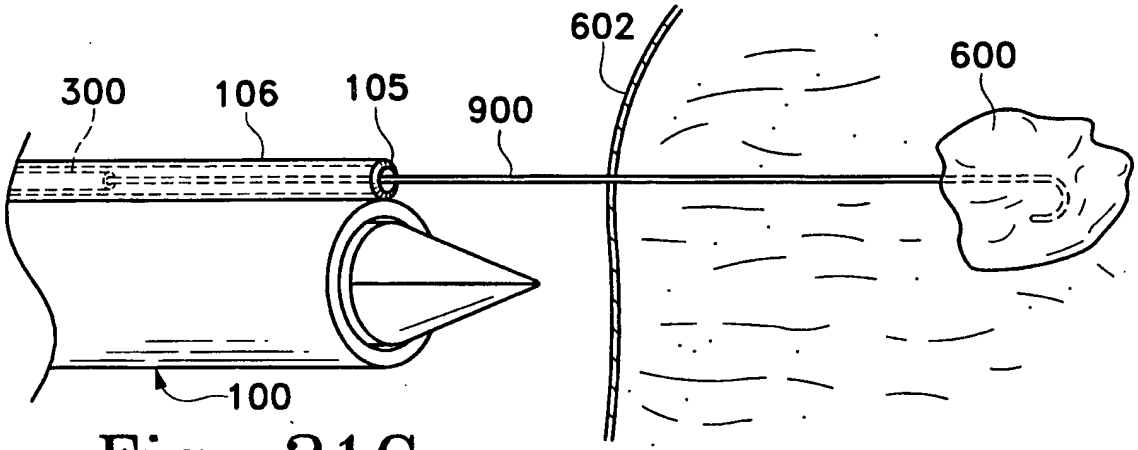


Fig. 21C

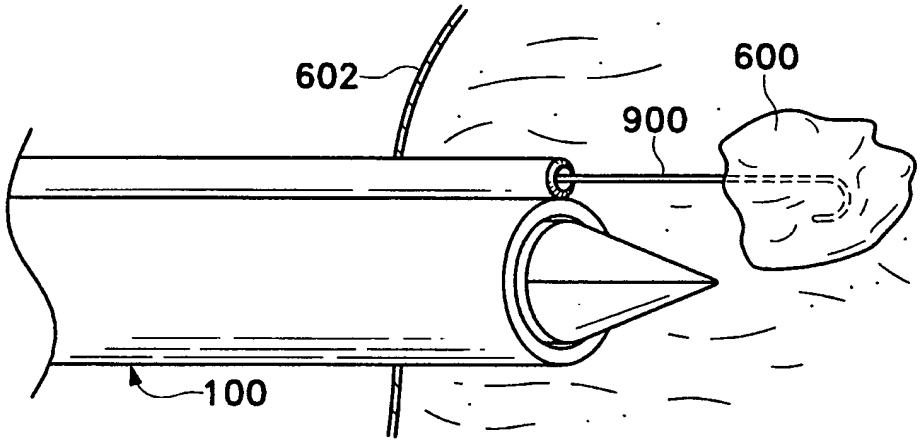


Fig. 21D

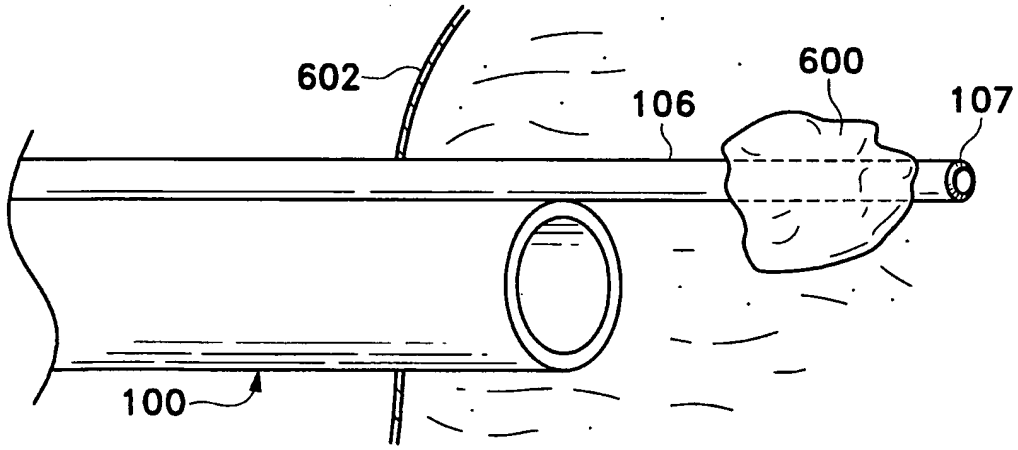


Fig. 21E

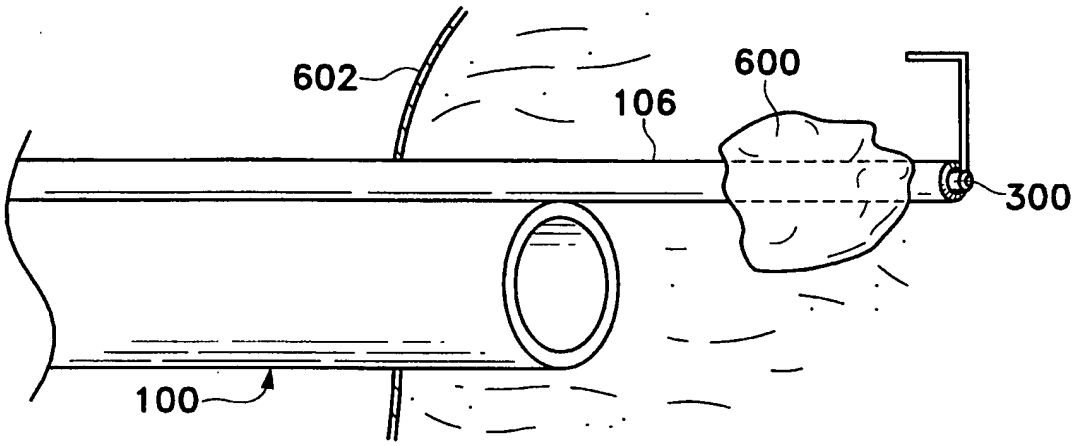


Fig. 21F

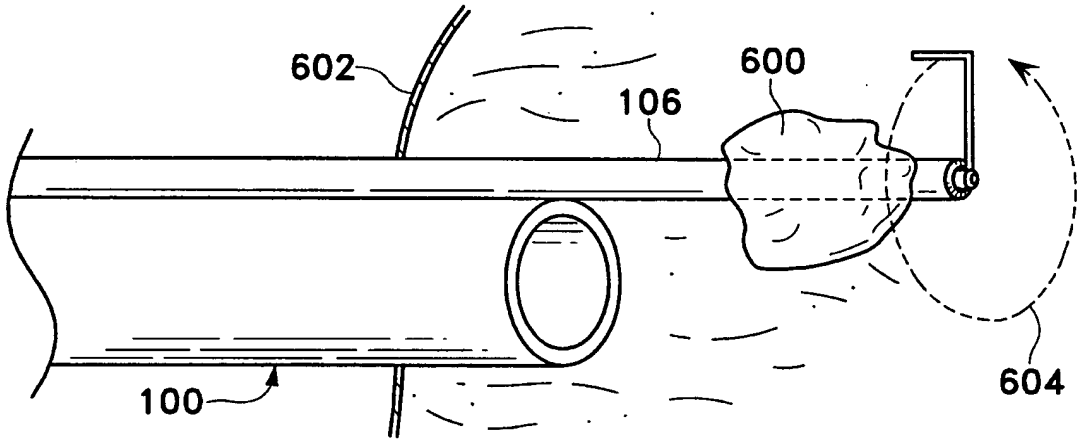


Fig. 21G

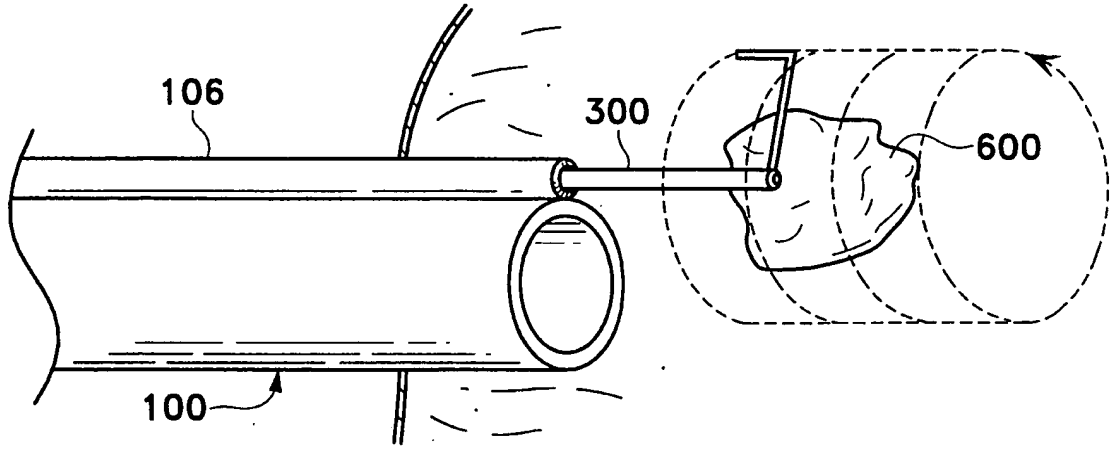


Fig. 21H

INTERNATIONAL SEARCH REPORT

International Application No
F../US 99/19660

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A61B10/00 A61B17/32

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A61B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2 729 210 A (SPENCER) 3 January 1956 (1956-01-03) column 3, last line; figures 2-4 ---	1
A	US 4 461 305 A (CIBLEY) 24 July 1984 (1984-07-24) abstract; figure 10 ---	1
A	US 5 709 697 A (RATCLIFFE) 20 January 1998 (1998-01-20) figures 25,26 ---	1
A	US 5 611 803 A (HEAVEN) 18 March 1997 (1997-03-18) figures 8,9 ---	1
	-/--	

[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

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Date of the actual completion of the international search	Date of mailing of the international search report
17 November 1999	01/12/1999

Name and mailing address of the ISA	Authorized officer
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INTERNATIONAL SEARCH REPORT

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A	US 3 175 554 A (STEWART) 30 March 1965 (1965-03-30) figures 10-12	1
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A	US 3 732 858 A (BANCO) 15 May 1973 (1973-05-15)	
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Form PCT/ISA/210 (continuation of second sheet) (July 1992)

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US 99/ 19660

Box I Observations where certain claims were found unsearchable (Continuation of item 1 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. [X] Claims Nos.: 35-63, 71-75
because they relate to subject matter not required to be searched by this Authority, namely:
Rule 39.1(iv) PCT - Method for treatment of the human or animal body by surgery

2. [ ] Claims Nos.:
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:

3. [ ] Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box II Observations where unity of invention is lacking (Continuation of item 2 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows:

1. [ ] As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.

2. [ ] As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.

3. [ ] As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:

4. [ ] No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:

Remark on Protest

[ ] The additional search fees were accompanied by the applicant's protest.

[ ] No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No
PCT/US 99/19660

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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(54) Title: ELECTROSURGICAL DEVICE FOR CELL NECROSIS INDUCTION

(57) Abstract

A cell necrosis apparatus includes an introducer with a distal end sufficiently sharp to penetrate tissue. An energy delivery device has a first set of RF electrodes and a second set of RF electrodes. Each RF electrode of the first and second sets has a tissue piercing distal end and is positionable in the introducer as the introducer is advanced through tissue. The first and second sets of RF electrodes are deployable with curvature from the introducer. The second set of RF electrodes is deployable a greater distance from the introducer than the first set of RF electrodes.

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CELL NECROSIS APPARATUS

BACKGROUND OF THE INVENTION

Field of the Invention

This invention relates generally to a cell necrosis apparatus, and more particularly to a cell necrosis apparatus with an introducer and deployable electrodes.

Description of the Related Art

Current open procedures for treatment of tumors are extremely disruptive and cause a great deal of damage to healthy tissue. During the surgical procedure, the physician must exercise care in not cutting the tumor in a manor that creates seeding of the tumor, resulting in metastasis. In recent years, development of products has been directed with an emphasis on minimizing the traumatic nature of traditional surgical procedures.

There has been a relatively significant amount of activity in the area of hyperthermia as a tool for treatment of tumors. It is known that elevating the temperature of tumors is helpful in the treatment and management of cancerous tissues. The mechanisms of selective cancer cell eradication by hyperthermia are not completely understood. However, four cellular effects of hyperthermia on cancerous tissue have been proposed, (i) changes in cell or nuclear membrane permeability or fluidity, (ii) cytoplasmic lysomal disintegration, causing release of digestive enzymes, (iii) protein thermal damage affecting cell respiration and the synthesis of DNA or RNA and (iv) potential excitation of immunologic systems. Treatment methods for applying heat to tumors include the use of direct contact radio-frequency

(RF) applicators, microwave radiation, inductively coupled RF fields, ultrasound, and a variety of simple thermal conduction techniques.

Among the problems associated with all of these procedures is the requirement that highly localized heat be produced at depths of several centimeters beneath the surface of the skin.

Attempts to use interstitial local hyperthermia have not proven to be very successful. Results have often produced nonuniform temperatures throughout the tumor. It is believed that tumor mass reduction by hyperthermia is related to thermal dose. Thermal dose is the minimum effective temperature applied throughout the tumor mass for a defined period of time. Because blood flow is the major mechanism of heat loss for tumors being heated, and blood flow varies throughout the tumor, more even heating of tumor tissue is needed to ensure effective treatment.

The same is true for ablation of the tumor itself through the use of RF energy. Different methods have been utilized for the RF ablation of masses such as tumors. Instead of heating the tumor it is ablated through the application of energy. This process has been difficult to achieve due to a variety of factors including, (i) positioning of the RF ablation electrodes to effectively ablate all of the mass, (ii) introduction of the RF ablation electrodes to the tumor site and (iii) controlled delivery and monitoring of RF energy to achieve successful ablation without damage to non-tumor tissue.

Thus, non-invasive procedures for providing heat to internal tissue have had difficulties in achieving substantial specific and selective treatment.

Examples illustrating the use of electromagnetic energy to ablate tissue are disclosed in: U.S. Patent No. 4,562,200; U.S. Patent No.

4,411,266; U.S. Patent No. 4,838,265; U.S. Patent No. 5,403,311; U.S. Patent No. 4,011,872; U.S. Patent No. 5,385, 544; and U.S. Patent No. 5,385,544.

There is a need for a cell necrosis apparatus with at least two electrodes that are deployable with curvature from an introducer. There is another need for a cell necrosis apparatus with at least two electrodes that are selectably deployable with curvature from an introducer to a desired deployed geometric configuration. There is yet a further need for a cell necrosis apparatus that provides deployable electrodes that create a variety of different geometric cell necrosis lesions.

SUMMARY OF THE INVENTION

Accordingly, an object of the invention is to provide a cell necrosis apparatus that provides tissue reduction at selected anatomical sites.

Another object of the invention is to provide a treatment apparatus to create cell necrosis.

Still another object of the invention is to provide a cell necrosis apparatus that has at least two electrodes which are deployable from an introducer with curvature and a third electrode which is deployable with minimal curvature.

Yet another object of the invention is to provide a cell necrosis apparatus with selectively deployed electrodes.

A further object of the invention is to provide a cell necrosis apparatus that is configured to deploy electrodes selectively at a tissue site to create a desired cell necrosis lesion.

These and other objects of the invention are achieved in a cell necrosis apparatus that includes an introducer with a distal end sufficiently sharp to penetrate tissue. An energy delivery device has a first set of RF electrodes and a second set of RF electrodes. Each RF electrode of the first and second sets has a tissue piercing distal end and is positionable in the introducer as the introducer is advanced through tissue. The first and second sets of RF electrodes are deployable with curvature from the introducer. The second set of RF electrodes is deployable a greater distance from the introducer than the first set of RF electrodes.

In another embodiment, the cell necrosis apparatus has an energy delivery device including a first RF electrode, a second RF electrode and a third RF electrode. Each of the first, second and third RF electrodes have a tissue piercing distal end and are positionable in the introducer as the

introducer is advanced through tissue. The first and second RF electrodes are selectably deployable with curvature from the introducer to a tissue site. The third RF electrode is deployable from the introducer with less curvature than the first and second RF electrodes.

In another embodiment, the cell necrosis apparatus has an energy delivery device with first and second RF electrodes. The first and second RF electrodes have tissue piercing distal ends and are positionable in the introducer as the introducer is advanced through tissue. The first and second RF electrodes are selectably advanceable with curvature from the introducer to a tissue site. A deployable member is included and has a tissue piercing distal end. The deployable member is positionable in the introducer as the introducer is advanced through tissue and deployable from the introducer with less curvature than the first and second RF electrodes. A sensor is coupled to the deployable member.

BRIEF DESCRIPTION OF THE FIGURES

Figure 1 is cross-sectional view of a cell necrosis apparatus of the present invention with two deployable electrodes and an deployable member at a selected cell necrosis tissue site.

Figure 2(a) illustrates a cross-sectional view of an embodiment of a cell necrosis apparatus of the present invention with a first and a second set of deployable electrodes.

Figure 2(b) illustrates the cell necrosis apparatus of Figure 2(a) positioned at a targeted cell necrosis tissue site.

Figure 3 illustrates an embodiment of a cell necrosis apparatus of the present invention with multiple sensors coupled to electrodes.

Figure 4 illustrates a spherical cross-section of an electrode utilized with a cell necrosis apparatus of the present invention.

Figure 5 illustrates an elliptical cross-section of an electrode utilized with a cell necrosis apparatus of the present invention.

Figure 6 illustrates a cross-section of an electrode utilized with a cell necrosis apparatus of the present invention with a larger cross-sectional length than its width.

Figure 7 illustrates a cross-section of an electrode utilized with a cell necrosis apparatus of the present invention with a flat-like external surface.

Figure 8 is a perspective view of a cell necrosis apparatus of the present invention that includes insulation sleeves positioned at exterior surfaces of the electrodes.

Figure 9 is a perspective view of a cell necrosis apparatus of the present invention that includes multiple insulation sleeves that circumferentially insulate selected sections of the electrodes.

Figure 10 is a perspective view of a cell necrosis apparatus of the present invention with insulation that extends along longitudinal sections of the electrodes to define adjacent longitudinal energy delivery surfaces.

Figure 11 is a cross-sectional view of the cell necrosis apparatus of Figure 10 taken along the lines 11-11.

Figure 12 is a perspective view of a cell necrosis apparatus of the present invention with insulation that extends along longitudinal sections of the electrodes and does not continue to distal ends of the electrodes.

Figure 13 is a cross-sectional view illustrating the positioning of electrodes adjacent to a selected tissue site with insulation that extends along a longitudinal surface of the electrodes and the insulation faces away from a central axis of the selected tissue site.

Figure 14 is a cross-sectional view illustrating the positioning of electrodes at a selected tissue site with insulation that extends along a longitudinal surface of the electrodes and the insulation faces toward a central axis of the selected tissue site.

Figure 15 is a close-up perspective view of a surface area of an electrode body at a distal end of an electrode of a cell necrosis apparatus of the present invention.

Figure 16 is a perspective view of a cell necrosis apparatus of the present invention with spacers associated with each deployed electrode.

Figure 17 is a cross-sectional view of a cell necrosis apparatus of the present invention illustrating a spacer, an associated electrode and insulation inside the spacer.

Figure 18 is a cross-sectional view of an embodiment of a cell necrosis apparatus of the present invention that includes a slidable member that engages a power source to a contact coupled to the electrodes.

Figure 19 is a cross-sectional view of the apparatus of Figure 18 with the slidable member pulled back and disengaging the power source from the electrodes.

Figure 20 is a block diagram illustrating the inclusion of a controller, electromagnetic energy source and other electronic components of the present invention.

Figure 21 is a block diagram illustrating an analog amplifier, analog multiplexer and microprocessor used with the present invention.

DETAILED DESCRIPTION

Referring to Figure 1, one embodiment of a cell necrosis apparatus 10 includes an introducer 12 with a distal end 14 sufficiently sharp to

penetrate tissue. An energy delivery device, generally denoted as 16, includes a first RF electrode 18 and a second RF electrode 20. Electrodes 18 and 20 are positionable in introducer 12 as introducer 12 advances through tissue. Electrodes 18 and 20 have tissue piercing distal ends 22 and 24, respectively. Electrodes 18 and 20 are selectably deployed with curvature from a distal end 14 or a side port formed in a distal portion 26 of introducer 12 to a selected tissue site 28. Tissue site 28 can be any tissue mass and can be a tumor to be ablated. Electrodes 18 and 20 are selectably deployed to be controllably positioned at a desired location relative to tissue site 28 that includes internal placement, external placement at a periphery of tissue site 28 and at any desired location relative to tissue site 28. The selectable deployment of electrodes 18 and 20 can be achieved with the amount of advancement of electrodes 18 and 20 from introducer 12, independent advancement of electrodes 18 and 20 from introducer 12, the lengths and/or sizes of energy delivery surfaces of electrodes 18 and 20, the variation in materials used for electrodes 18 and 20 as well as variation of geometric configuration of electrodes 18 and 20 in their deployed states.

Electrodes 18 and 20 are in compacted positions while they are positioned in introducer 12. As electrodes 18 and 20 are advanced from introducer 12 they move to a deployed state from their compacted configurations. Any number of electrodes can be included in energy delivery device 16. The electrodes of energy delivery device 16 can be deployed simultaneously, in pairs, in sets and one at a time. An electrode advancement member 30 is coupled to energy delivery device 16. Electrode advancement member 30 can be actuated by the physician by movement of a proximal end 32 relative to a longitudinal axis of introducer 12.

Introducer 12 can be flexible. In one embodiment, introducer 12 is sufficiently flexible to pierce tissue, and move in any desired direction through tissue to tissue site 28. In another embodiment, introducer 12 is sufficiently flexible to reverse its direction of travel and move in direction back upon itself. In one embodiment, introducer 12 is more flexible than electrodes 18 and 20.

When introducer 12 reaches tissue site 28, including but not limited to a solid lesion, energy delivery device 16 is deployed preferably from distal end 14 of introducer 12. Energy delivery device 16 can also be deployed from side ports formed in the body of introducer 12. In the deployed state energy delivery device 16 becomes expanded from its compacted configuration in introducer 12 and is selectively positioned relative to tissue site 12. Electrodes 18 and 20 can be portioned within an interior of tissue site 12, at the exterior of tissue site 12 as well as combinations thereof. Electrodes 18, 20 as well as third, fourth, fifth, etc. electrodes are advanceable different lengths from distal end 14 of introducer 12. In one embodiment, the electrodes of deployed energy delivery device 16 are positioned equally distant a central axis of tissue site 28. Volumetric cell necrosis can proceed from the interior, exterior of tissue site 28 as well as various combinations thereof with each deployed electrode of energy delivery device 16 in order to create a selectable and predictable cell necrosis.

Electrodes 18 and 20 can be made of a variety of conductive materials, both metallic and non-metallic. One suitable material is type 304 stainless steel of hypodermic quality. In some applications, all or a portion of electrodes 18 and 20 can be made of a shaped memory metal, such as NiTi, commercially available from Raychem Corporation, Menlo Park,

California. A radiopaque marker 21 can be coated on electrodes 18 and 20 for visualization purposes.

Electrodes 18 and 20 can have different lengths that are advanced from distal end 14 of introducer 12. The lengths can be determined by the actual physical length of electrodes 18 and 20, the length of an energy delivery surface of electrodes 18 and 20 and the length of electrodes 18 and 20 that is not covered by an insulator. Suitable lengths include but are not limited to 17.5 cm, 25.0 cm. and 30.0 cm. The actual lengths of electrodes 18 and 20 depends on the location of tissue site 28 to be ablated, its distance from the skin, its accessibility as well as whether or not the physician chooses a laparoscopic, percutaneous or other procedure.

A deployable member 34 can be coupled to electrode advancement member 30. Deployable member 34 can provide a variety of different functions including but not limited to the placement of a sensor at a selected tissue site to measure/monitor temperature and/or impedance. Additionally, all or a portion of deployable member 34 can be an RF electrode operable in bi-polar or mono-polar modes. Deployable member 34 can also be a groundpad electrode.

A sensor 36 can be coupled to deployable member 34 at a distal end 38, or at any physical location of deployable member 34. In this manner, temperature and/or impedance is measured or monitored at a distal portion of tissue site 28 or at any position in or external to tissue site 28. Deployable member 34 is deployable from distal end 14 of introducer 12 with less curvature than electrodes 18 and 20. Deployable member 34 can be deployable from distal end 14 without substantially any curvature.

Sensor 36 permits accurate measurement of temperature at tissue site 28 in order to determine, (i) the extent of cell necrosis, (ii) the amount of

cell necrosis, (iii) whether or not further cell necrosis is needed and (iv) the boundary or periphery of the ablated mass. Further, sensor 36 reduces non-targeted tissue from being destroyed or ablated.

Sensor 36 is of conventional design, including but not limited to thermistors, thermocouples, resistive wires, and the like. A suitable thermal sensor 36 includes a T type thermocouple with copper constantene, J type, E type, K type, fiber optics, resistive wires, thermocouple IR detectors, and the like. It will be appreciated that sensor 36 need not be a thermal sensor.

Sensor 36 measures temperature and/or impedance to permit monitoring and a desired level of cell necrosis to be achieved without destroying too much tissue. This reduces damage to tissue surrounding the targeted mass to be ablated. By monitoring the temperature at various points within and outside of the interior of tissue site 28, a determination of the selected tissue mass periphery can be made, as well as a determination of when cell necrosis is complete. If at any time sensor 36 determines that a desired cell necrosis temperature is exceeded, then an appropriate feedback signal is received at an energy source 40 coupled to energy delivery device 16 which then regulates the amount of electromagnetic energy delivered to electrodes 18 and 20.

Energy source 40 can be an RF power supply, an ultrasound energy source, a microwave generator, a resistive heating source, a laser and the like. Microwave antenna, optical fibers, resistive heating elements and ultrasound transducers can be substituted for electrodes 18 and 20. When energy source 40 is an RF power supply, 5 to 200 watts, preferably 5 to 100, and still more preferably 5 to 50 watts of electromagnetic energy is delivered from energy source 40 to the electrodes of energy delivery device 16 without impeding out the electrodes.

Electrodes 18 and 20 are electromagnetically coupled to energy source 40. The coupling can be direct from energy source 40 to each electrode 18 and 20 respectively, or indirect by using a collet, sleeve and the like which couples one or more electrodes to energy source 40.

Referring now to Figure 2(a), another embodiment of apparatus 10 is shown. Apparatus 10 includes a first set 42 of RF electrodes and a second set 44 of RF electrodes. First and second sets 42 and 44 can include one, two, three, four, five, etc, number of RF electrodes. As illustrated in Figure 2, first set 42 includes electrodes 46 and 48, and second set 44 includes electrodes 50 and 52. It will be appreciated that first and second sets 42 and 44 can include more or less electrodes than are illustrated in Figure 2. Electrodes 46, 48, 50 and 52 have tissue piercing distal ends, are positionable in introducer 12 in compacted states, and advanceable to deployed states from distal end 14 with curvature from introducer 12. First set 42 is deployable a greater distance from distal end 14 than second set 44.

First and second sets 42 and 44 are coupled to electrode advancement member 30 and can be simultaneously or individually deployed from distal end 14. Optionally coupled to first set 42, second set 44 and/or electrode advancement member 30 is deployable member 34. Again, deployable member 34 can be coupled to a sensor 36 and all or a portion of deployable member 34 may be an RF electrode.

Figure 2(b) illustrates the use of multiple sensors 36. Sensors 36 can be coupled to all or some of electrodes 46, 48, 50 and/or 52 at different positions of the electrodes. In various embodiments, sensors are positioned at distal ends of electrodes 46 through 52, at positions that are adjacent to distal end 14 of introducer 12, and at sites that are somewhere intermediate between the distal and proximal portions of deployed lengths of the

electrodes. Deployable member 34 can include sensors at distal and proximal portions of its deployed length in tissue site 28. The placement of sensors 36 at different locations provides a measurement of temperature and/or impedance, and a determination of the level of cell necrosis, created at tissue site 28.

As shown in Figure 3, electrodes 18, 20, 46, 48, 50 and 52, collectively "electrodes 18", can each be coupled to one or more sensors 36. Sensors 36 can be at exterior surfaces of electrodes 18 at their distal ends, intermediate sections as well as adjacent to distal end 14 of introducer 12. Some or all of electrodes 18 and deployable member 34 may have a hollow lumen by which a variety of different fluidic medium can be introduced from proximal to distal ends. Suitable fluidic media include but are not limited to electrolytic solutions, chemotherapeutic agents, drugs, medicaments, gene therapy agents, contrast agents and the like.

Electrode 18, as well as deployable member 34, can have a variety of different geometric cross-sections. Electrodes 18 can be made of conductive solid or hollow straight wires of various shapes such as round, flat, triangular, rectangular, hexagonal, elliptical and the like. Figures 4 and 5 illustrate circular and elliptical cross-sections. In Figure 6, the cross-section has a greater length "L" than a width of "W". If Figure 7, the cross-sectional is elongated. In various embodiments, the cross-sectional has a greater length than a width in order to enhance ultrasonic viewability.

Each, a portion of all electrodes 18, as well as deployable member 34, have an exterior surface that is wholly or partially insulated and provide a non-insulated area which is an energy delivery surface. In Figure 8, two electrodes 18 include insulation 54. In the embodiment of Figure 8,

insulation 54 is a sleeve that can be fixed or adjustable. The active area of electrodes 18 is non-insulated and provides an energy delivery surface 56.

In the embodiment illustrated in Figure 9, insulation 54 is formed at the exterior of electrodes 18 in circumferential patterns, leaving a plurality of energy delivery surfaces 56. Referring now to the embodiment of Figures 10 and 11, insulation 54 extends along a longitudinal exterior surface of electrodes 18. Insulation 54 can extend along a selected distance along a longitudinal length of electrodes 18 and around a selectable portion of a circumference of electrodes 18. In various embodiments, sections of electrodes 18 can have insulation 54 along selected longitudinal lengths of electrodes 18 as well as completely surround one or more circumferential sections of electrodes 18. Insulation 54 positioned at the exterior of electrodes 18 can be varied to define any desired shape, size and geometric energy delivery surface 56.

In Figure 12, insulation 54 is disposed on only one section of a deployed length of electrodes 18. Energy delivery surfaces 56 are at distal portions of electrodes 18 as well as on longitudinal surfaces adjacent to insulation 54. In Figure 13, insulation 54 extends along a longitudinal length of electrodes 18 can face toward a central axis 58 of tissue site 28 and energy delivery surface 56 faces towards in a direction toward the central axis 58. In Figure 14, insulation 54 extends along a longitudinal length of electrodes 18 and faces away from central axis 58 with energy delivery surface 56 facing away from central axis 58. In the embodiments illustrated in Figures 12 and 13, three electrodes 18 are positioned inside or outside of a periphery of tissue site 28. It will be appreciated that any number of electrodes 18 can be deployed with and without insulation to created a selectable cell necrosis pattern.

Electrodes 18 are selectably deployable from introducer 12 with curvature to create any desired geometric area of cell necrosis. The selectable deployment is achieved by having electrodes 18 with, (i) different advancement lengths from introducer 12, (ii) different deployed geometric configurations, (iii) variations in cross-sectional geometries, (iv) selectable insulation provided at each and/or all of the deployed electrodes 18, or (v) the use of adjustable insulation.

Deployed electrodes 18 can create a variety of different geometric cell necrosis zones including but not limited to spherical, semi-spherical, spheroid, triangular, semi-triangular, square, semi-square, rectangular, semi-rectangular, conical, semi-conical, quadrilateral, semi-quadrilateral, semi-quadrilateral, rhomboidal, semi-rhomboidal, trapezoidal, semi-trapezoidal, combinations of the preceding, geometries with non-planar sections or sides, free-form and the like.

In one embodiment, the ultrasonic visibility of electrodes 18 through is enhanced by creating a larger electrode distal end surface area 60. Surface area 60 is the amount of the electrode body that is at the distal end of electrodes 18. Referring now to Figure 15 the distal end of electrode 18 has at cut angle of at least 25°, and in another embodiment the cut angle is at least 30°. This creates a larger surface area 60. The distal end of deployable member 34 can also have these cut angles.

Referring to Figures 16 and 17, each or selected electrodes 18 and deployable member 34 can have an associated spacer 62. Spacers 62 are advanceable from distal end 14 of introducer 12 and can be coupled to advancement member 30. Spacers 62 create a physical spacing that separates the deployed electrodes 18 from each other. The spacing created by spacers 62 also forms an area in tissue site 28 where there is reduced or

very little cell necrosis. Positioned within spacers 62 is an insulation 64 that electrically and electromagnetically isolates electrodes 18 from spacers 62.

As illustrates in Figures 18 and 19, apparatus 10 can include a slidable member 66 that provides an electrical connection between energy delivery 16 and energy source 40. Slidable member 66 can be advancement member 30 or a handpiece. In one embodiment, slidable member 66 has one or two electrical contact pads 68 which can be resistor strips. When slidable member is moved in a distal direction relative to distal end 14 of introducer 12 resistor strips 68 becomes engaged with a contact 70 (Figure 18). Contact 70 is coupled to energy delivery device 16. When resistor strips 68 are engaged with contact 70, power and energy is delivered from energy source to electrodes 18. Slidable member 66 is then moved in a distal direction and resistor strips become un-engaged with contact 70 and the delivery of power from energy source 40 is disrupted (Figure 19). The employment of slidable member 66 provides a convenient energy delivery device 16 on and off mechanism at the hand of the physician.

Resistor strips 68 can be used as sensors to recognize a variable setting of one or all of electrodes 18 of energy delivery device 16. Resistor strips 68 can be used to measure resistance at a setting so that a change in the resistance value can be measured as slidable member 66 is moved and a corresponding change in the energy delivery surface corresponding to the electrodes 18. The resistance value can be correlated to determine an optimal power in delivering energy from energy source 40. Gap sensors, including but not limited to lasers and ultrasound, can be used to determine the variable setting.

Referring now to Figure 20, a feedback control system 72 is connected to energy source 40, sensors 36 and energy delivery device 16.

Feedback control system 72 receives temperature or impedance data from sensors 36 and the amount of electromagnetic energy received by energy delivery device 16 is modified from an initial setting of cell necrosis energy output, cell necrosis time, temperature, and current density (the "Four Parameters"). Feedback control system 72 can automatically change any of the Four Parameters. Feedback control system 72 can detect impedance or temperature and change any of the Four Parameters. Feedback control system 72 can include a multiplexer to multiplex different electrodes 18 and a temperature detection circuit that provides a control signal representative of temperature or impedance detected at one or more sensors 36. A microprocessor can be connected to the temperature control circuit.

The user of apparatus 10 can input an impedance value which corresponds to a setting position located at apparatus 10. Based on this value, along with measured impedance values, feedback control system 72 determines an optimal power and time need in the delivery of RF energy. Temperature is also sensed for monitoring and feedback purposes. Temperature can be maintained to a certain level by having feedback control system 72 adjust the power output automatically to maintain that level.

In another embodiment, feedback control system 72 determines an optimal power and time for a baseline setting. Ablation volumes or lesions are formed at the baseline first. Larger lesions can be obtained by extending the time of ablation after a center core is formed at the baseline. A completion of lesion creation can be checked by advancing energy delivery device 16 from distal end 14 of introducer 12 to a desired lesion size and by monitoring the temperature at the periphery of the lesion.

In another embodiment, feedback control system 72 is programmed so the delivery of energy to energy delivery device 16 is paused at certain

intervals at which time temperature is measured. By comparing measured temperatures to desired temperatures feedback control system 72 can terminate or continue the delivery of power to electrodes 18 for an appropriate length of time.

The following discussion pertains particularly to the use of an RF energy source and RF electrodes but applies to other energy delivery devices and energy sources including but not limited to microwave, ultrasound, resistive heating, coherent and incoherent light, and the like.

Current delivered to electrodes 18 is measured by a current sensor 74. Voltage is measured by voltage sensor 76. Impedance and power are then calculated at power and impedance calculation device 78. These values can then be displayed at user interface and display 80. Signals representative of power and impedance values are received by controller 82.

A control signal is generated by controller 82 that is proportional to the difference between an actual measured value, and a desired value. The control signal is used by power circuits 84 to adjust the power output in an appropriate amount in order to maintain the desired power delivered at energy delivery device 16.

In a similar manner, temperatures detected at sensors 36 provide feedback for determining the extent of cell necrosis, and when a completed cell necrosis has reached the physical location of sensors 36. The actual temperatures are measured at temperature measurement device 86 and the temperatures are displayed at user interface and display 80. A control signal is generated by controller 82 that is proportional to the difference between an actual measured temperature, and a desired temperature. The control signal is used by power circuits 84 to adjust the power output in an appropriate amount in order to maintain the desired temperature delivered at

the respective sensor 36. A multiplexer can be included to measure current, voltage and temperature, at the numerous sensors 36, and energy is delivered to energy delivery device 16. A variable electrode setting 88 is coupled to controller 82.

Controller 82 can be a digital or analog controller, or a computer with software. When controller 82 is a computer it can include a CPU coupled through a system bus. On this system can be a keyboard, a disk drive, or other non-volatile memory systems, a display, and other peripherals, as are known in the art. Also coupled to the bus are a program memory and a data memory.

User interface and display 80 includes operator controls and a display. Controller 82 can be coupled to imaging systems, including but not limited to ultrasound, CT scanners, X-ray, MRI, mammographic X-ray and the like. Further, direct visualization and tactile imaging can be utilized.

The output of current sensor 74 and voltage sensor 76 is used by controller 82 to maintain a selected power level at energy delivery device 16. The amount of RF energy delivered controls the amount of power. A profile of power delivered can be incorporated in controller 82, and a preset amount of energy to be delivered can also be profiled.

Circuitry, software and feedback to controller 82 result in process control, and the maintenance of the selected power, and are used to change, (i) the selected power, including RF, microwave, laser and the like, (ii) the duty cycle (on-off and wattage), (iii) bi-polar or mono-polar energy delivery and (iv) infusion medium delivery, including flow rate and pressure. These process variables are controlled and varied, while maintaining the desired delivery of power independent of changes in voltage or current, based on temperatures monitored at sensors 36.

Referring now to Figure 21, current sensor 74 and voltage sensor 76 are connected to the input of an analog amplifier 90. Analog amplifier 90 can be a conventional differential amplifier circuit for use with sensors 36. The output of analog amplifier 90 is sequentially connected by an analog multiplexer 46 to the input of A/D converter 92. The output of analog amplifier 90 is a voltage which represents the respective sensed temperatures. Digitized amplifier output voltages are supplied by A/D converter 92 to a microprocessor 96. Microprocessor 96 may be Model No. 68HCII available from Motorola. However, it will be appreciated that any suitable microprocessor or general purpose digital or analog computer can be used to calculate impedance or temperature.

Microprocessor 96 sequentially receives and stores digital representations of impedance and temperature. Each digital value received by microprocessor 96 corresponds to different temperatures and impedances.

Calculated power and impedance values can be indicated on user interface and display 80. Alternatively, or in addition to the numerical indication of power or impedance, calculated impedance and power values can be compared by microprocessor 96 with power and impedance limits. When the values exceed predetermined power or impedance values, a warning can be given on user interface and display 80, and additionally, the delivery of RF energy can be reduced, modified or interrupted. A control signal from microprocessor 96 can modify the power level supplied by energy source 40.

The foregoing description of a preferred embodiment of the invention has been presented for purposes of illustration and description. It is not intended to be exhaustive or to limit the invention to the precise forms

disclosed. Obviously, many modifications and variations will be apparent to practitioners skilled in this art. It is intended that the scope of the invention be defined by the following claims and their equivalents.

What is claimed is:

CLAIMS

1. A cell necrosis apparatus, comprising:

an introducer with a distal end sufficiently sharp to penetrate tissue; and

an energy delivery device including a first set of RF electrodes and a second set of RF electrodes, each RF electrode of the first and second set having a tissue piercing distal end and positionable in the introducer as the introducer is advanced through tissue, the first and second sets of RF electrodes being deployable with curvature from the introducer, wherein the second set of RF electrodes is deployable a greater distance than the first set of RF electrodes from the introducer.

2. The apparatus of claim 1, further comprising:

a deployable member with a tissue piercing distal end, the deployable member positionable in the introducer as the introducer is advanced through tissue, the deployable member being deployable from the introducer with less curvature than the RF electrodes of the first and second sets of RF electrodes.

3. The apparatus of claim 2, wherein at least a portion of the deployable member is an RF electrode.

4. The apparatus of claim 2, further comprising:

a sensor coupled to a distal portion of the deployable member.

5. The apparatus of claim 3, further comprising:

a sensor coupled to a distal portion of the deployable member.

6. The apparatus of claim 2, further comprising:
an insulator positioned at an exterior of the deployable member.

7. The apparatus of claim 3, further comprising:
an insulator positioned at least a portion of the deployable member.

8. The apparatus of claim 1, wherein at least a portion of the RF electrodes of the first and second set of RF electrodes has a non-circular cross-sectional geometry.

9. The apparatus of claim 8, wherein the non-circular cross-sectional geometry includes a width and length, wherein the length is greater than the width.

10. The apparatus of claim 1, wherein at least a portion of the RF electrodes of the first and second set of RF electrodes has a non-circular cross-sectional geometry with a sufficient exterior surface area to be ultrasonically viewable.

11. The apparatus of claim 1, wherein at least a portion of the RF electrodes of the first and second set of RF electrodes has a tissue piercing distal end that is ultrasonically viewable.

12. The apparatus of claim 1, wherein at least a portion of the RF electrodes of the first and second set of RF electrodes has a tissue piercing distal end that has a cut angle of at least 25°.

13. The apparatus of claim 1, wherein at least a portion of the RF electrodes of the first and second set of RF electrodes has a tissue piercing distal end that has a cut angle of at least 30°.

14. The apparatus of claim 2, wherein the tissue piercing distal end of the deployable member is ultrasonically viewable.

15. The apparatus of claim 1, wherein the tissue piercing distal end of the deployable member has a cut angle of at least 25°.

16. The apparatus of claim 1, wherein the tissue piercing distal end of the deployable member has a cut angle of at least 30°.

17. The apparatus of claim 1, further comprising:

a spacer member coupled to an RF electrode of the first and second set of RF electrodes.

18. The apparatus of claim 17, wherein the spacer member is advanceable from the introducer.

19. The apparatus of claim 17, wherein the spacer member is advanceable from the introducer with the RF electrode.

20. The apparatus of claim 17, wherein the spacer member includes an RF insulation that electrically isolates the RF electrode from the spacer member.

21. The apparatus of claim 20, wherein at least a portion of the spacer member is an RF electrode.

22. The apparatus of claim 1, further comprising:
a first sensor coupled to the energy delivery device.

23. The apparatus of claim 1, further comprising:
a first sensor and a second sensor coupled to an electrode of the first set of RF electrodes.

24. The apparatus of claim 23, wherein the first and second sensors are coupled to different exterior surface sites of the electrode.

25. The apparatus of claim 23, further comprising:
a third sensor coupled to an electrode of the second set of RF electrodes.

26. The apparatus of claim 25, further comprising:
a fourth sensor coupled to the electrode of the second set of RF electrodes.

27. The apparatus of claim 25, wherein the third and fourth sensors are coupled to different exterior surface sites of the electrode.

28. The apparatus of claim 23, further comprising:

a third sensor and a fourth sensor coupled to different exterior surface sites of an electrode of the second set of RF electrodes.

29. The apparatus of claim 1, further comprising:

a first sensor coupled to a first electrode of the first set of RF electrodes and a second sensor coupled to a second electrode of the first set of RF electrodes.

30. The apparatus of claim 29, further comprising:

a third sensor coupled to a first electrode of the second set of RF electrodes.

31. The apparatus of claim 30, further comprising:

a fourth sensor coupled to a second electrode of the second set of RF electrodes.

32. The apparatus of claim 1, wherein the first set of RF electrodes includes a first electrode and a second electrode, and the second set of RF electrodes includes a third electrode and a fourth electrode.

33. The apparatus of claim 1, further comprising:

a first insulation member positioned at an exterior surface of a first electrode of the first set of RF electrodes.

34. The apparatus of claim 33, further comprising:

a second insulation member positioned at an exterior surface of a second electrode of the first set of RF electrodes.

35. The apparatus of claim 1, further comprising:

a first insulation member coupled to a first electrode of the first set of RF electrodes, the first insulation member including a first insulation section that extends circumferentially around a first exterior site of the first electrode, and a second insulation section that extends circumferentially around a second exterior site of the first electrode, the first electrode having an active energy delivery surface positioned between the first and second insulation sections.

36. The apparatus of claim 35, further comprising:

a second insulation member coupled to a second electrode of the first set of RF electrodes, the second insulation member including a first insulation section that extends circumferentially around a first exterior site of the second electrode, and a second insulation section that extends circumferentially around a second exterior site of the of the second electrode, the second electrode having an active energy delivery surface positioned between the first and second insulation sections.

37. The apparatus of claim 36, further comprising:

a third insulation member coupled to a first electrode of the second set of RF electrodes, the third insulation member including a first insulation section that extends circumferentially around a first exterior site of the first electrode, and a second insulation section that extends circumferentially around a second exterior site of the first electrode, the first electrode having an active energy delivery surface positioned between the first and second insulation sections.

38. The apparatus of claim 37, further comprising:

a fourth insulation member coupled to a second electrode of the second set of RF electrodes, the fourth insulation member including a first insulation section that extends circumferentially around a first exterior site of the second electrode, and a second insulation section that extends circumferentially around a second exterior site of the second electrode, the second electrode having an active energy delivery surface positioned between the first and second insulation sections.

39. The apparatus of claim 1, further comprising:

a first insulation member coupled to a first electrode of the first set of RF electrodes, the first insulation member extending along a first longitudinal exterior surface of the first electrode and leaving an non-insulated active energy delivery surface extending along a second longitudinal exterior surface of the first electrode.

40. The apparatus of claim 39, further comprising:

a second insulation member coupled to a second electrode of the first set of RF electrodes, the second insulation member extending along a first longitudinal exterior surface of the second electrode and leaving an non-insulated active energy delivery surface extending along a second longitudinal exterior surface of the second electrode.

41. The apparatus of claim 40, further comprising:

a third insulation member coupled to a first electrode of the second set of RF electrodes, the third insulation member extending along a first longitudinal exterior surface of the first electrode and leaving an non-insulated active energy delivery surface extending along a second longitudinal exterior surface of the first electrode.

42. The apparatus of claim 41, wherein the first, second and third insulation members are each positioned to face toward a central axis of a selected tissue site.

43. The apparatus of claim 41, wherein the first, second and third insulation members are positioned to face away from a central axis of a selected tissue site.

44. The apparatus of claim 41, further comprising:

a fourth insulation member coupled to a second electrode of the second set of RF electrodes, the fourth insulation member extending along a first longitudinal exterior surface of the second electrode and leaving an

non-insulated active energy delivery surface extending along a second longitudinal exterior surface of the second electrode.

45. The apparatus of claim 41, further comprising:

a fourth insulation member coupled to a second electrode of the second set of RF electrodes, the second insulation member extending along a first longitudinal exterior surface of the second electrode and leaving an non-insulated active energy delivery surface extending along a second longitudinal exterior surface of the first electrode.

46. The apparatus of claim 45, wherein the first, second, third and fourth insulation members are each positioned to face toward a central axis of a selected tissue site.

47. The apparatus of claim 45, wherein the first, second, third and fourth insulation members are positioned to face away from a central axis of a selected tissue site.

48. A cell necrosis apparatus, comprising:

an introducer with a distal end sufficiently sharp to penetrate tissue; and

an energy delivery device including a first RF electrode, a second RF electrode and a third RF electrode, each of the first, second and third RF electrodes having a tissue piercing distal end and positionable in the introducer as the introducer is advanced through tissue, the first and second RF electrodes being selectably deployable with curvature from the

introducer to a tissue site, the third RF electrode being deployable from the introducer with less curvature than the first and second RF electrodes.

49. The apparatus of claim 48, further comprising:

a slidable member with a proximal portion positionable in a proximal portion of the introducer; and

an electrode contact member positioned in the proximal portion of the introducer.

50. The apparatus of claim 49, wherein the electrode contact member is coupled to the energy delivery device.

51. The apparatus of claim 50, wherein the slidable member includes a sensor coupled to the slidable member.

52. The apparatus of claim 51, wherein the sensor is engagable with the electrode contact member to coupled an energy source to the energy delivery device.

53. The apparatus of claim 48, wherein the third electrode is deployable from the introducer substantially without curvature.

54. The apparatus of claim 48, further comprising:

an RF electrode advancement member coupled to the first set of RF electrodes, the second set of RF electrodes and the third RF electrode.

55. A cell necrosis apparatus, comprising:

an introducer with a distal end sufficiently sharp to penetrate tissue; and

an energy delivery device including a first RF electrode and a second RF electrode each having a tissue piercing distal end and positionable in the introducer as the introducer is advanced through tissue, the first and second RF electrodes being selectably deployable with curvature from the introducer to a tissue site;

a deployable member, the deployable member having a tissue piercing distal end and positionable in the introducer as the introducer is advanced through tissue, the deployable member being deployable from the introducer with less curvature than the first and second RF electrodes; and

a sensor coupled to the deployable member.

56. The apparatus of claim 55, wherein the sensor is positioned at a distal portion of the deployable member.

57. The apparatus of claim 55, wherein the sensor is positioned at the distal end of the deployable member.

58. The apparatus of claim 55, further comprising:

an advancement member coupled to the first and second RF electrodes.

59. The apparatus of claim 58, wherein the advancement member is coupled to the deployable member.

60. The apparatus of claim 55, wherein the deployable member is an RF electrode.

61. The apparatus of claim 55, wherein the deployable member is a groundpad electrode.

62. The apparatus of claim 55, wherein the energy delivery device operates in a mono-polar manner.

63. The apparatus of claim 55, wherein the energy delivery device operates in a bi-polar manner.

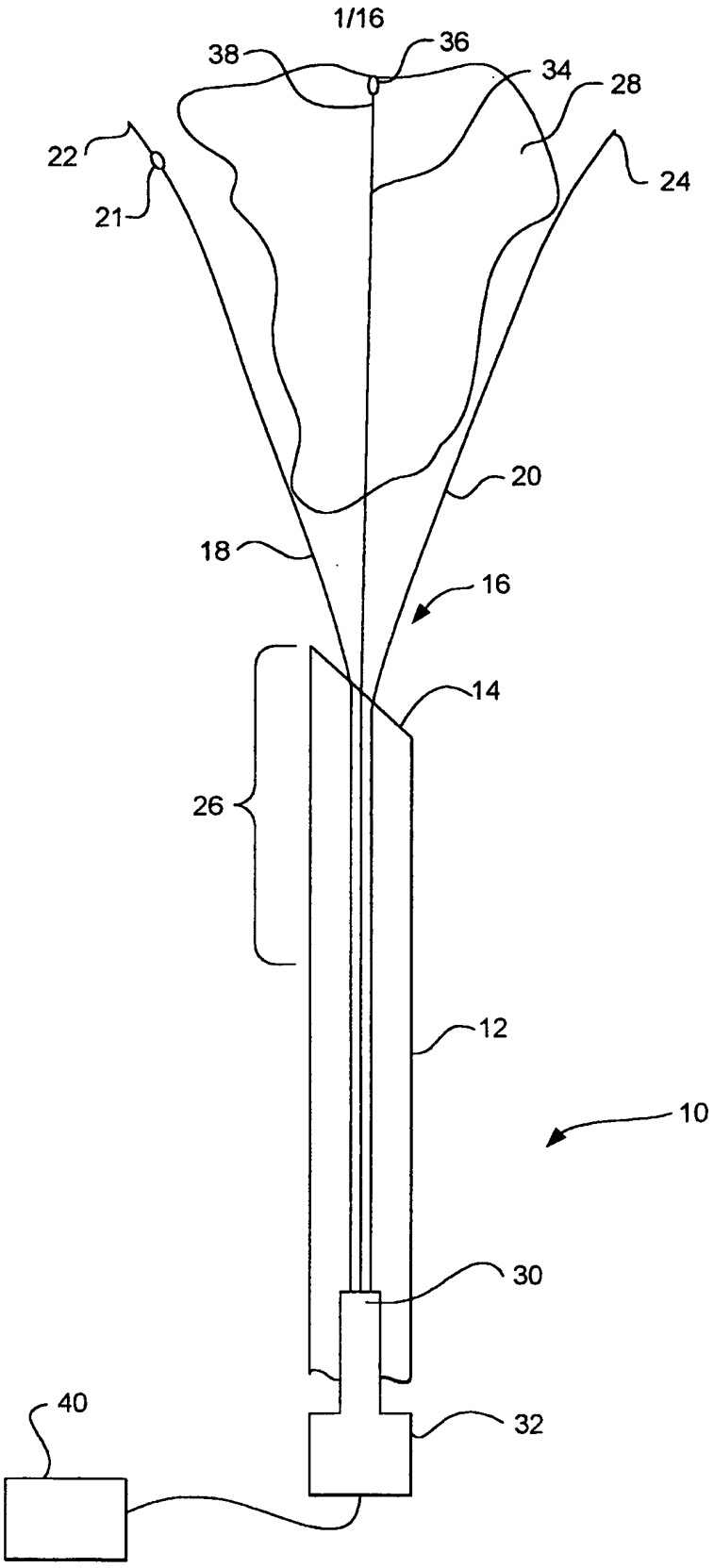

FIG. 1

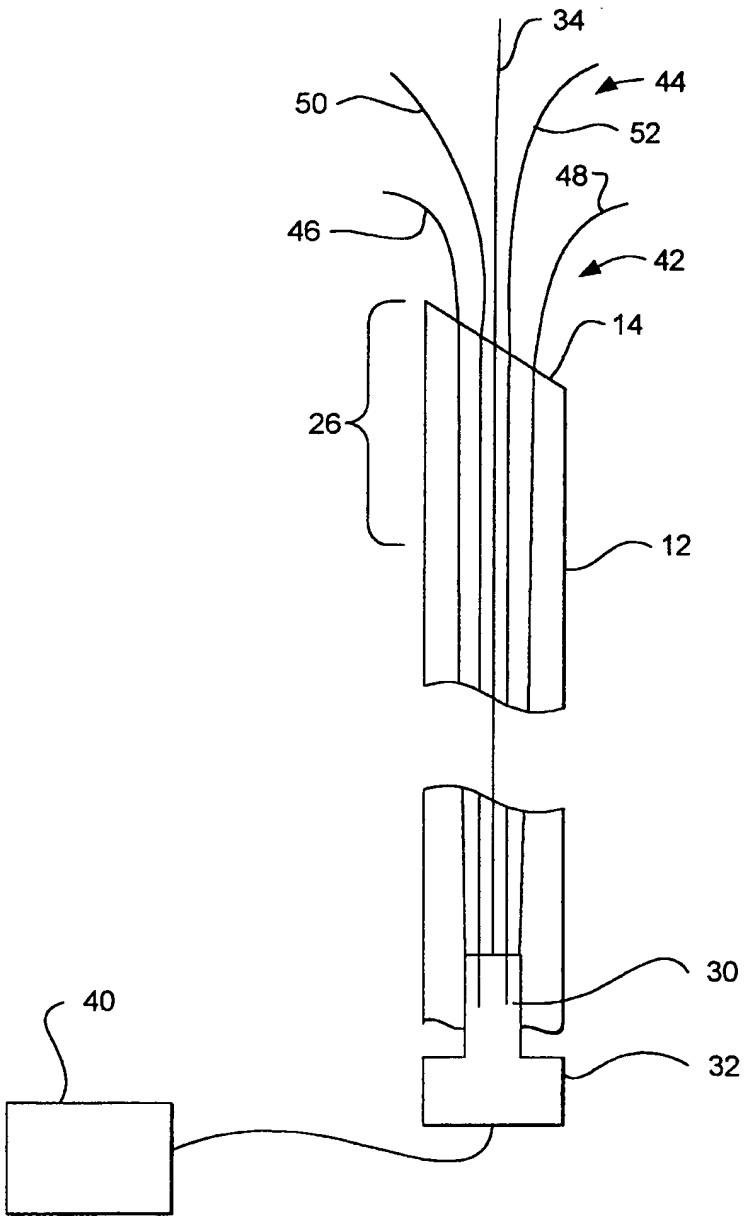

FIG. 2(a)

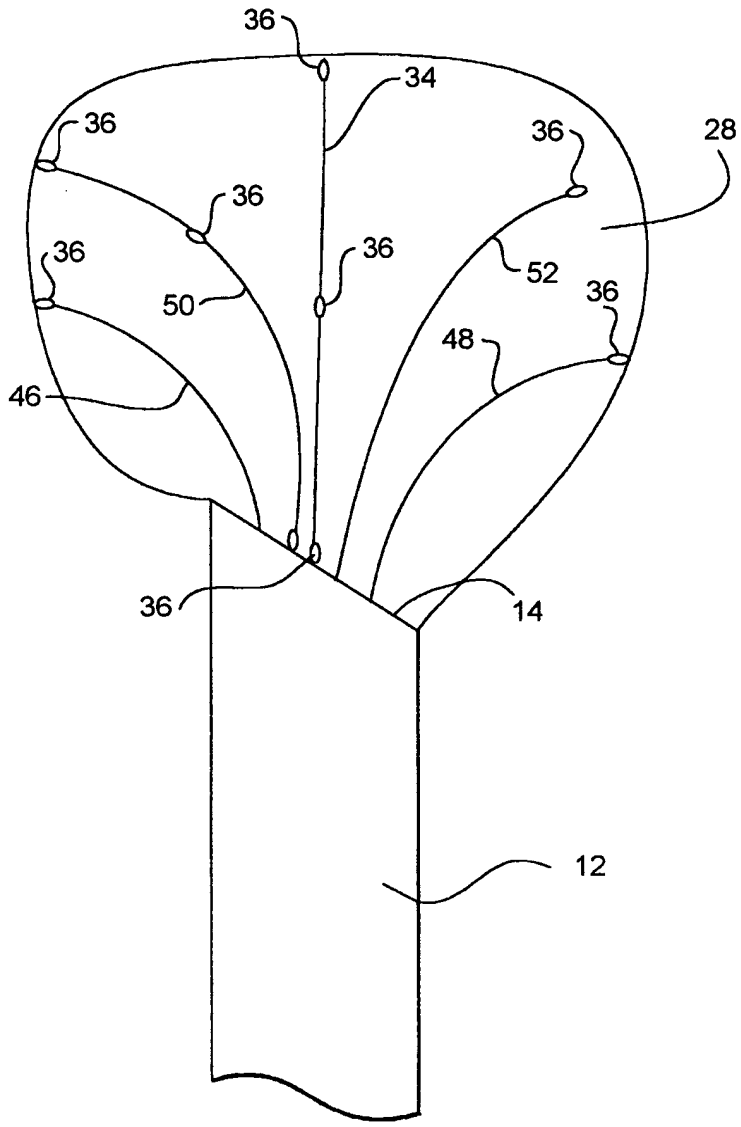

FIG. 2(b)

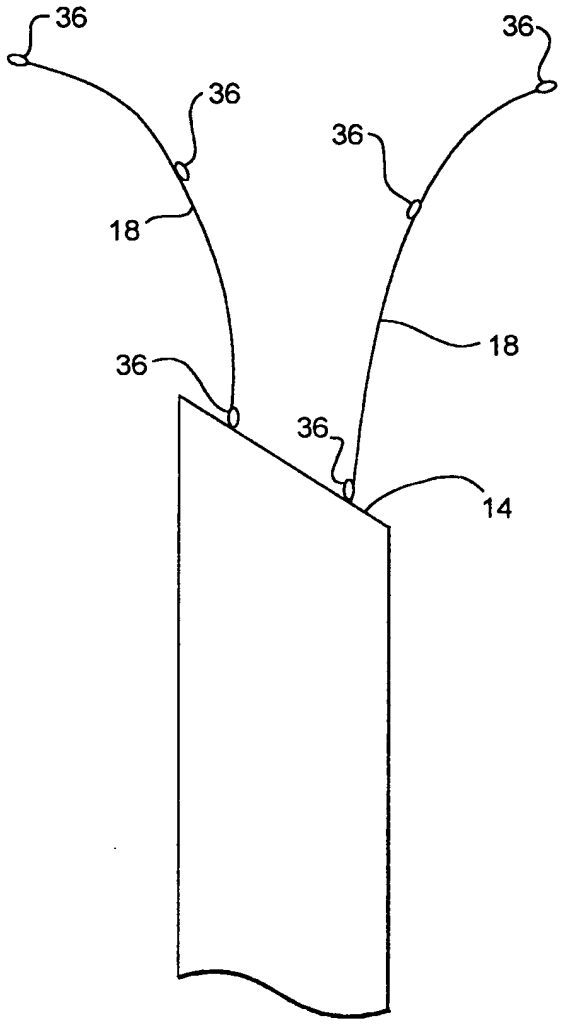

FIG. 3

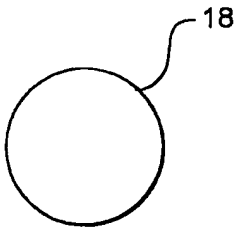

FIG. 4

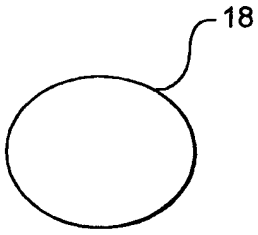

FIG. 5

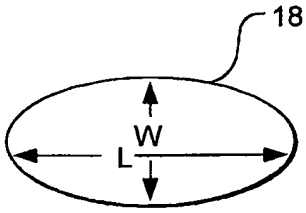

FIG. 6

FIG. 7

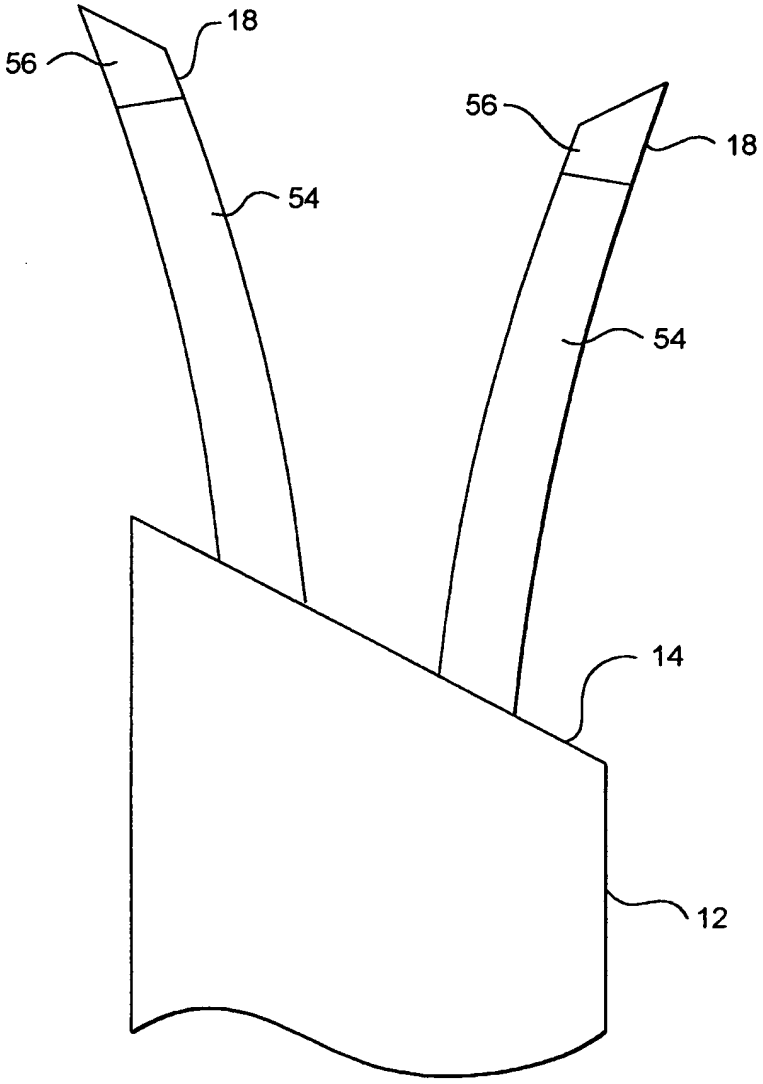

FIG. 8

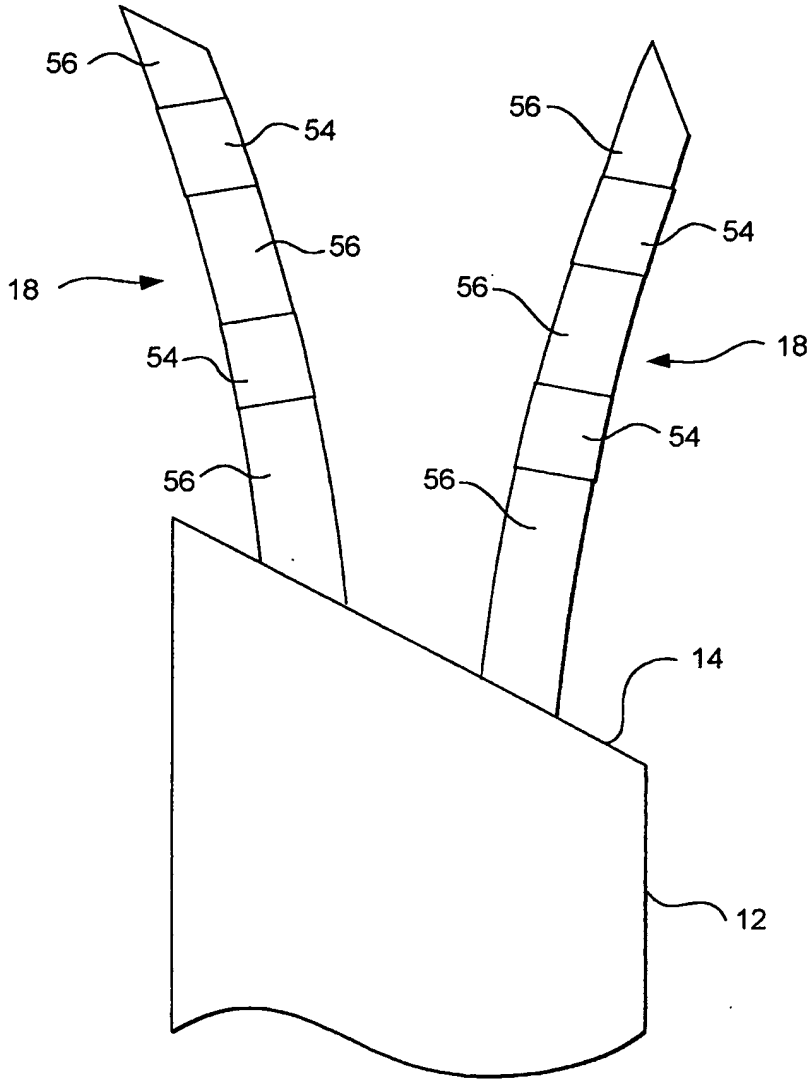

FIG. 9

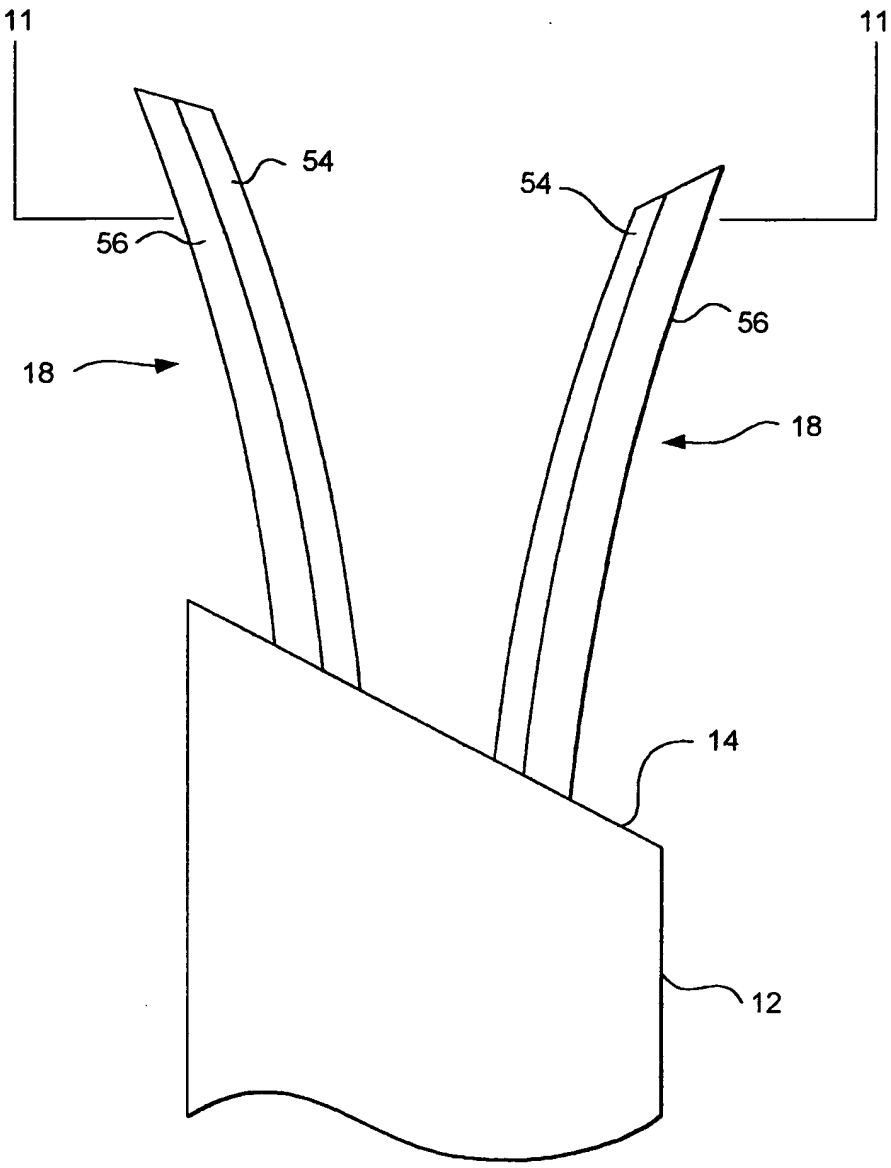

FIG. 10

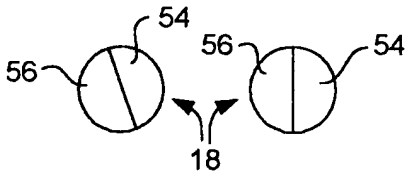

FIG. 11

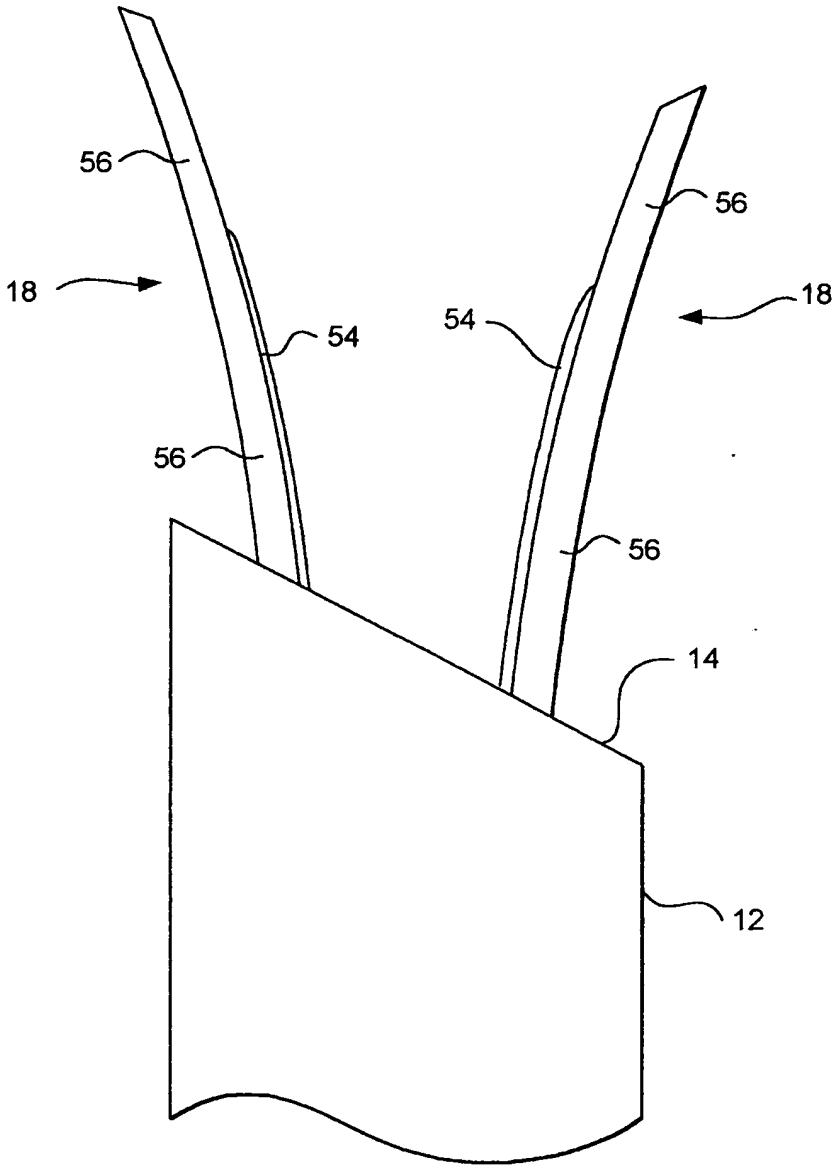

FIG. 12

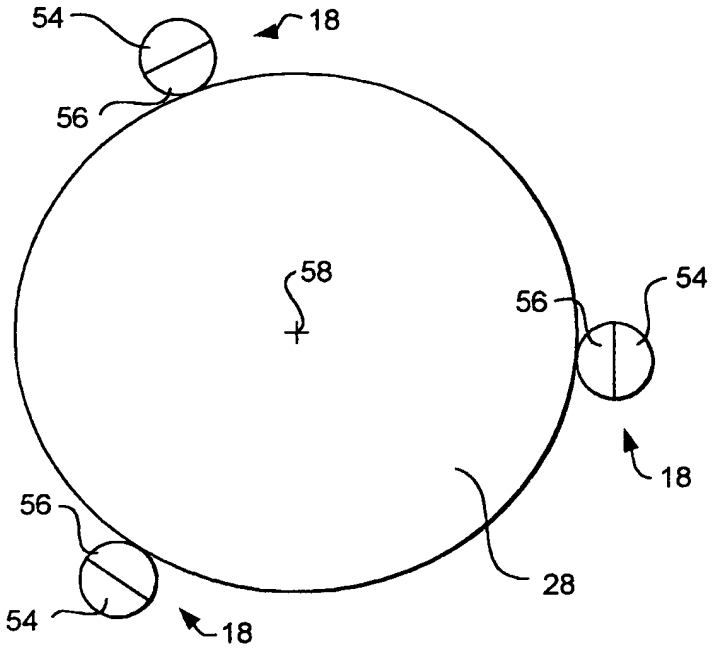

FIG. 13

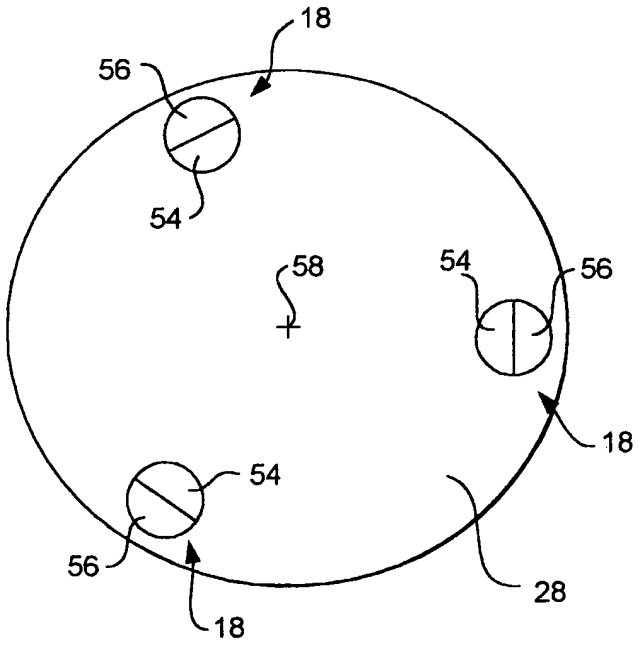

FIG. 14

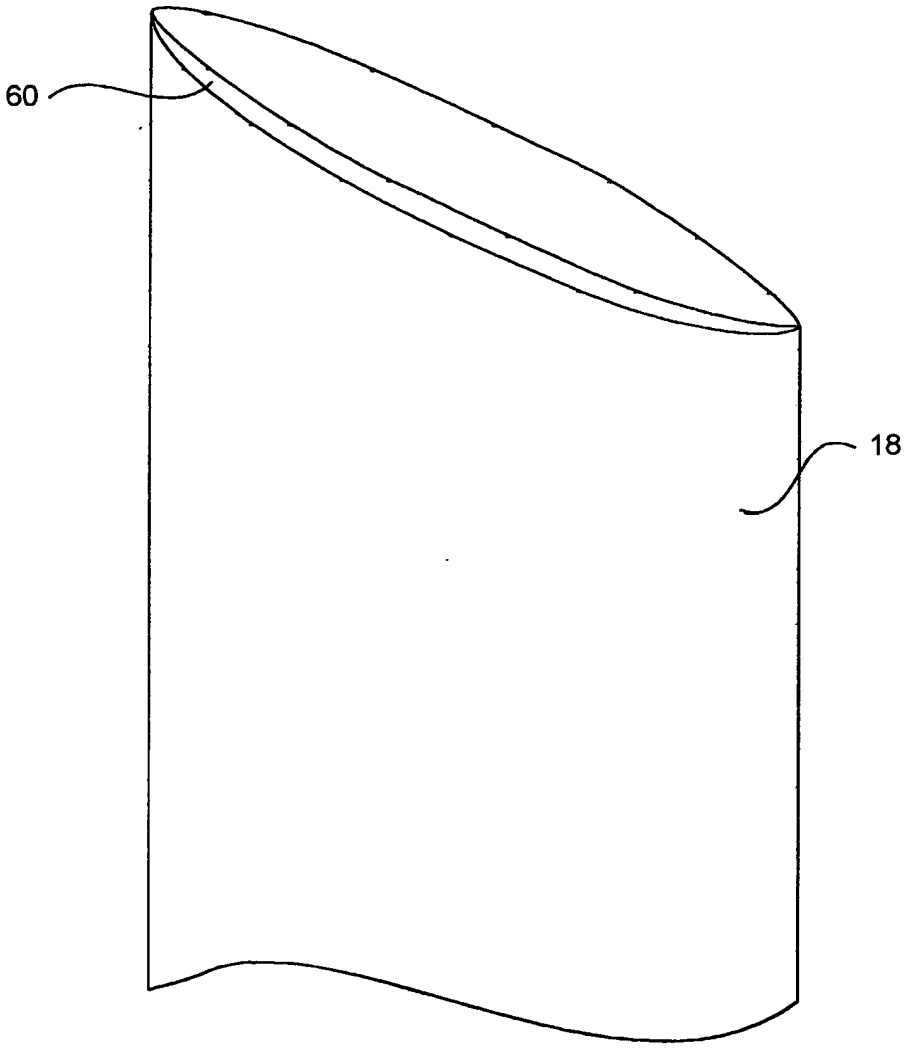

FIG. 15

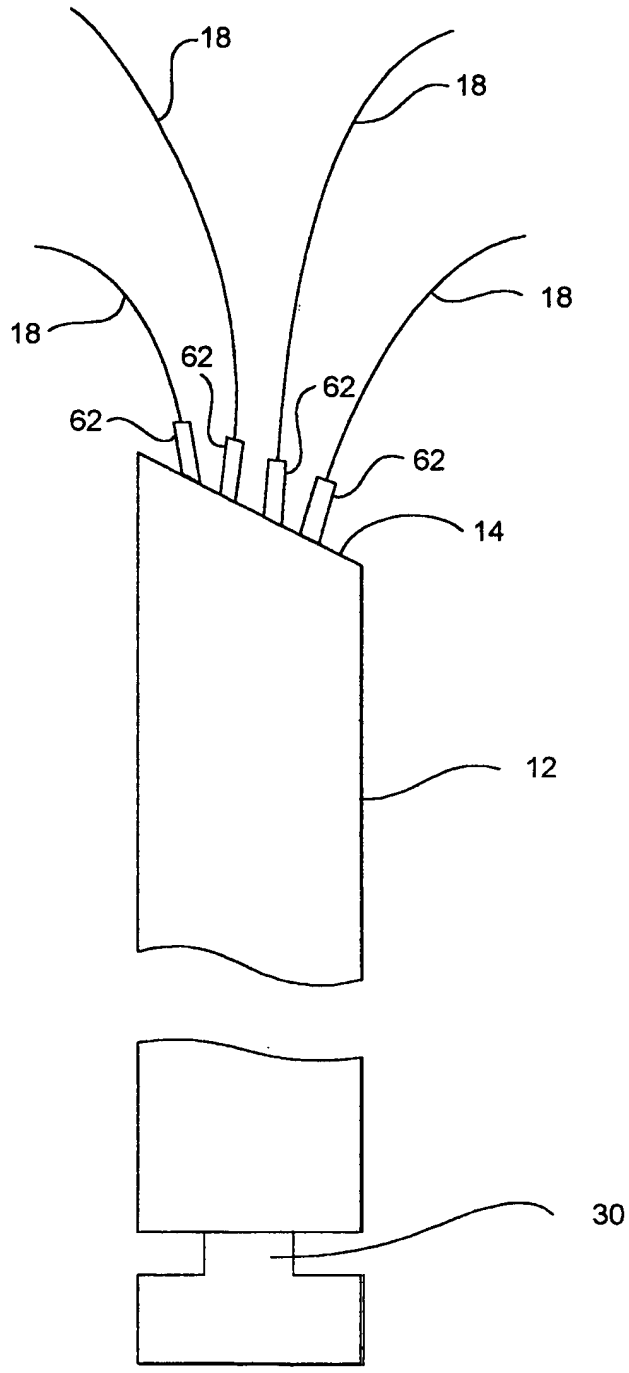

FIG. 16

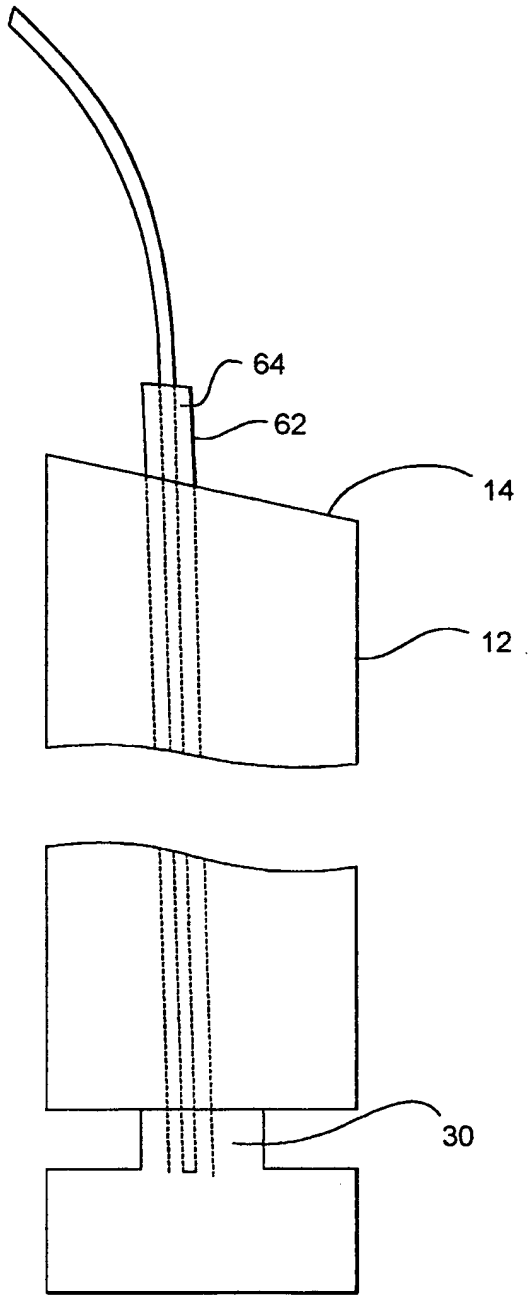

FIG. 17

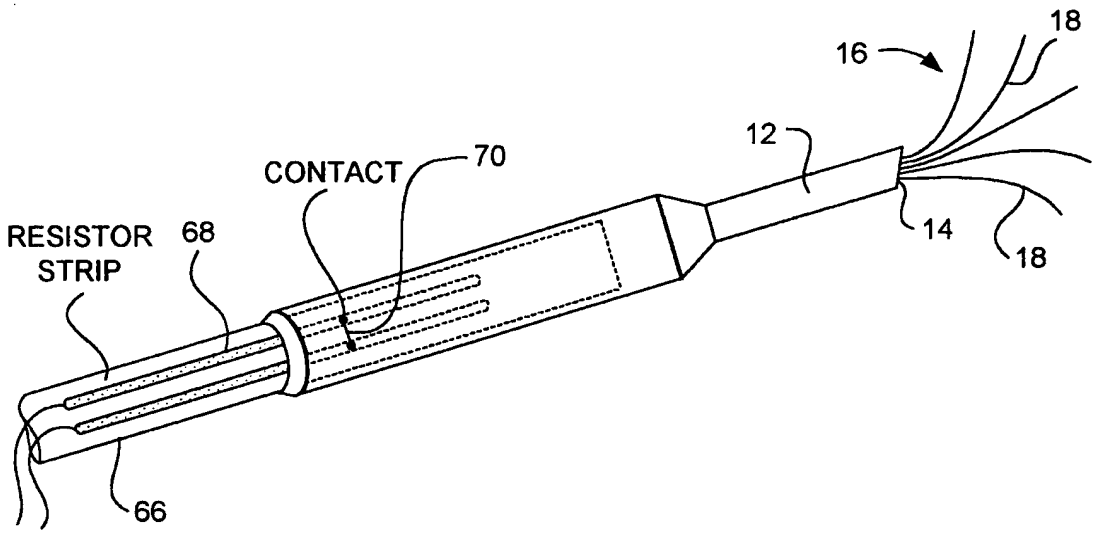
18
16
12
CONTACT
70
RESISTOR
STRIP
68
14
18
66

FIG. 18

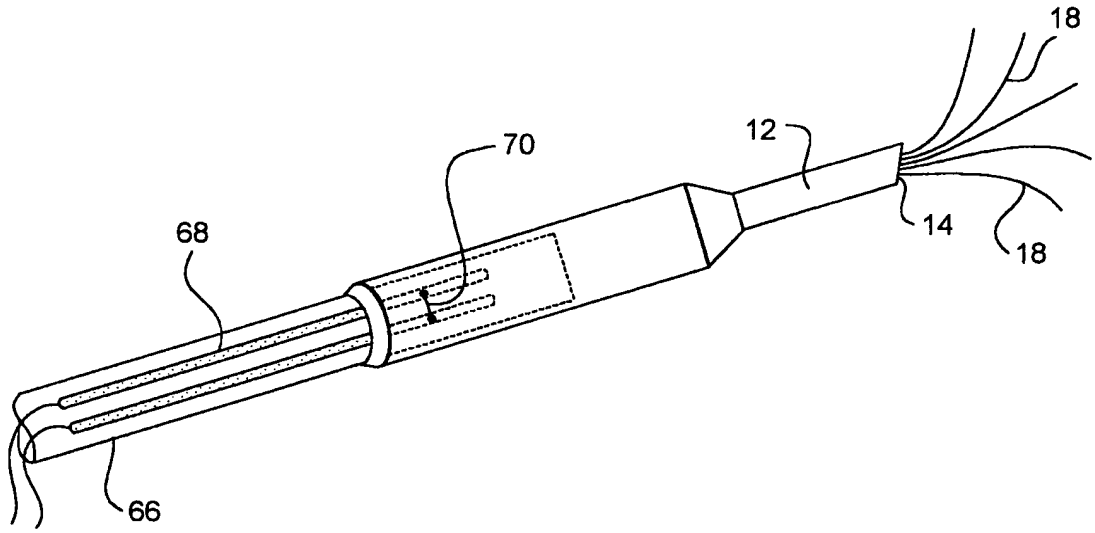
18
12
70
68
14
18
66

FIG. 19

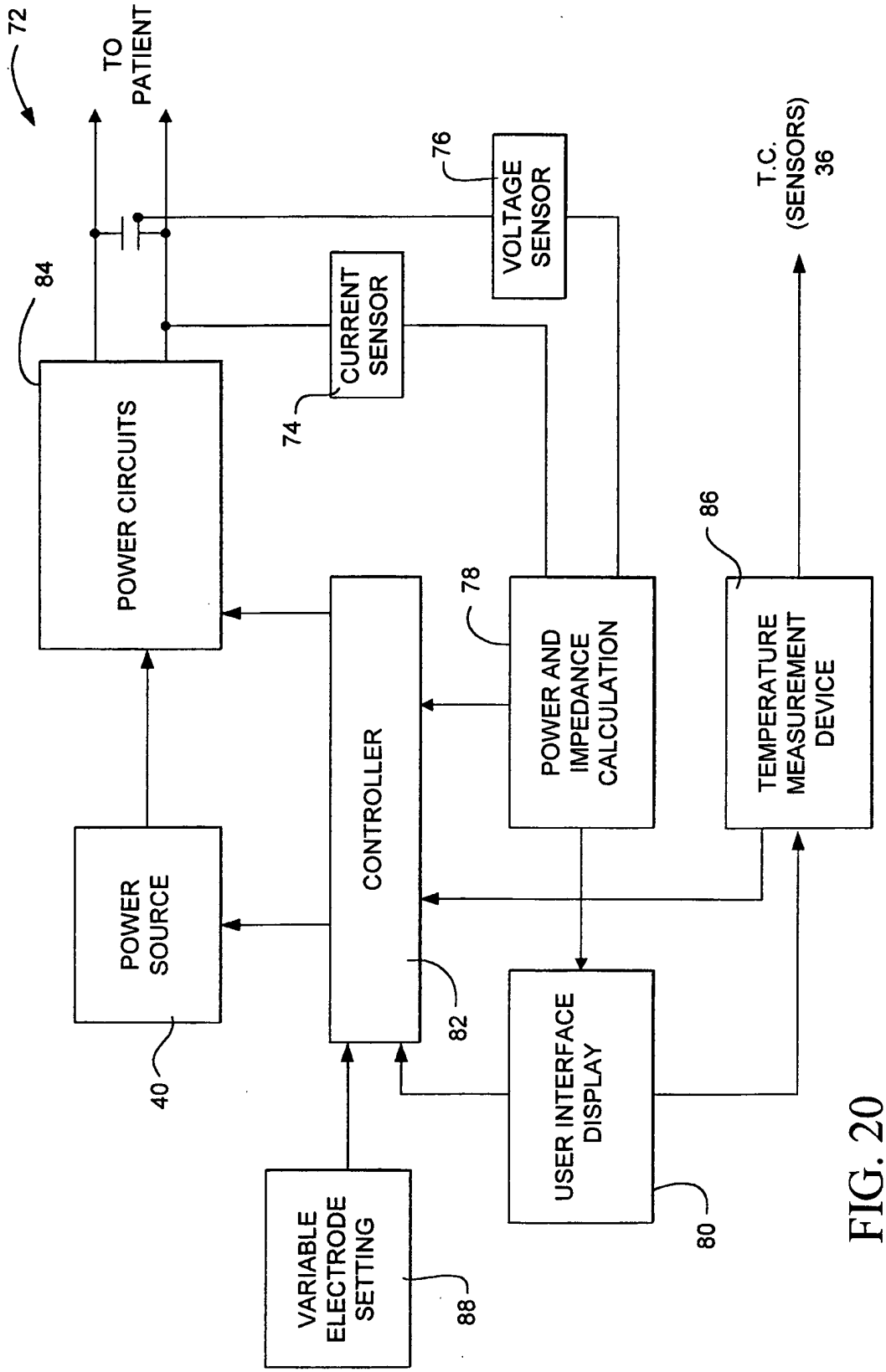
72
TO PATIENT
76
VOLTAGE SENSOR
T.C. (SENSORS) 36
84
CURRENT SENSOR
74
POWER CIRCUITS
86
78
POWER AND IMPEDANCE CALCULATION
TEMPERATURE MEASUREMENT DEVICE
CONTROLLER
POWER SOURCE
82
40
USER INTERFACE DISPLAY
80
VARIABLE ELECTRODE SETTING
88

FIG. 20

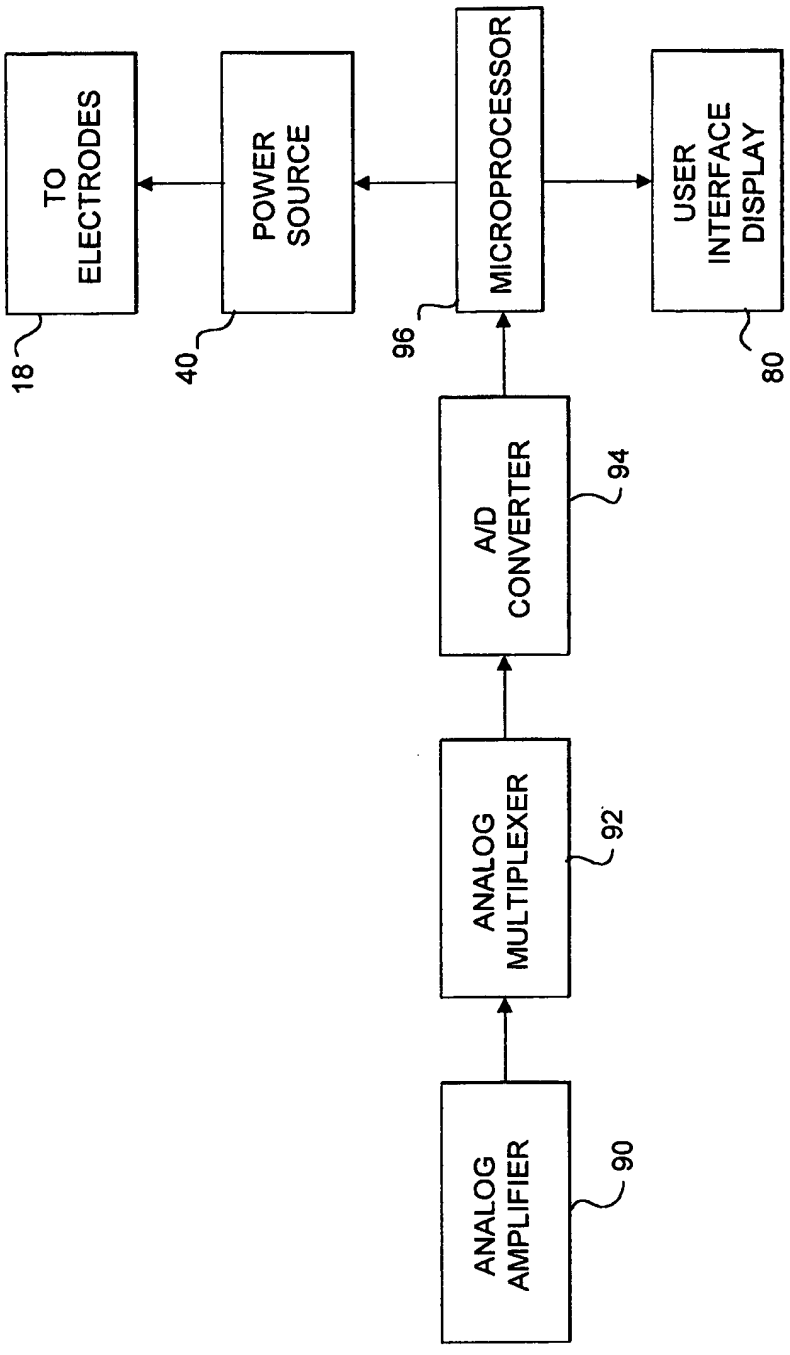
ANALOG AMPLIFIER
90
ANALOG MULTIPLEXER
92
A/D CONVERTER
94
MICROPROCESSOR
96
USER INTERFACE DISPLAY
80
POWER SOURCE
40
TO ELECTRODES
18

FIG. 21